

EXHIBIT 31

Robert Drillien - Confidential

Page 1

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UNITED STATES DISTRICT COURT

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FOR THE DISTRICT OF DELAWARE

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BAVARIAN NORDIC A/S,)

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Plaintiff,)

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V.) Civil Action No.

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ACAMBIS INC. and) 05-614

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ACAMBIS, PLC,)

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Defendants.)

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Deposition of ROBERT DRILLIEN

13

Washington, DC

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Friday, November 24, 2006

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20 JOB NO. 177833

21 PAGES 1-96

22 Reported by: Denise Vickery, RMR-CRR

<p style="text-align: right;">Page 2</p> <p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5 November 24, 2006</p> <p>6 8:11 a.m.</p> <p>7</p> <p>8 Deposition of ROBERT DRILLIEN, held at the offices of:</p> <p>9</p> <p>10 BINGHAM McCUTCHEN LLP</p> <p>11 The Washington Harbour</p> <p>12 3000 K Street NW, Suite 300</p> <p>13 Washington, DC 20007-5116</p> <p>14</p> <p>15 Pursuant to notice, before Denise Dobner Vickery, a</p> <p>16 Registered Merit Reporter, Notary Public of the</p> <p>17 District of Columbia.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>	<p style="text-align: right;">Page 4</p> <p style="text-align: center;">I N D E X</p> <p>1</p> <p>2</p> <p>3 EXAMINATION OF ROBERT DRILLIEN PAGE</p> <p>4 BY MR. COSTON 5</p> <p>5</p> <p>6</p> <p>7 DRILLIEN DEPOSITION EXHIBITS: PAGE</p> <p>8 No. 1 Expert Report of Robert Drillien. 5</p> <p>9 2 Expert Report of Louis P. Berneman. 49</p> <p>10 3 Pertinent Facts. 52</p> <p>11 4 Expert Report of Ashley J. Stevens. 88</p> <p>12 5 Expert Report and/or Legal Opinion of</p> <p>13 Prof. Dr. Dres. H.C. Joseph Straus. 89</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22 **Exhibits attached.**</p>
<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES:</p> <p>2 For the Plaintiff:</p> <p>3 BINGHAM McCUTCHEN LLP</p> <p>4 The Washington Harbour</p> <p>5 3000 K Street NW, Suite 300</p> <p>6 Washington, DC 20007-5116</p> <p>7 202-339-8951</p> <p>8 Eapennington@bingham.com</p> <p>9 BY: Edward A. Pennington, Esq.</p> <p>10</p> <p>11</p> <p>12 For the Defendants:</p> <p>13 VENABLE LLP</p> <p>14 575 7th Street NW</p> <p>15 Washington, DC 20004-1601</p> <p>16 202-344-4829</p> <p>17 Wdcoston@venable.com</p> <p>18 BY: William D. Coston, Esq.</p> <p>19</p> <p>20 ALSO PRESENT:</p> <p>21 Prof. Dr. Li Westerlund, Bavarian Nordic</p> <p>22</p>	<p style="text-align: right;">Page 5</p> <p>1 Thereupon,</p> <p>2 ROBERT DRILLIEN</p> <p>3 was called for examination, and, after having been duly</p> <p>4 sworn or affirmed, was examined and testified as</p> <p>5 follows:</p> <p>6 EXAMINATION BY COUNSEL FOR DEFENDANTS</p> <p>7 BY MR. COSTON:</p> <p>8 Q. Good morning, Dr. Drillien.</p> <p>9 A. Good morning, Mr. Coston.</p> <p>10 Q. Are you the same Robert Drillien who authored</p> <p>11 an expert report for submission in the case in the</p> <p>12 District of Delaware captioned Bavarian Nordic versus</p> <p>13 Acambis?</p> <p>14 A. Yes.</p> <p>15 MR. COSTON: Let's mark as Exhibit 1</p> <p>16 your expert report.</p> <p>17 (Thereupon, a document was marked for</p> <p>18 identification Exhibit No. 1.)</p> <p>19 BY MR. COSTON:</p> <p>20 Q. Which I think is actually incomplete because</p> <p>21 we failed to copy the attachment to it. We'll proceed</p> <p>22 with this version at least for right now. Can you</p>

2 (Pages 2 to 5)

<p style="text-align: right;">Page 6</p> <p>1 identify Exhibit 1?</p> <p>2 MR. PENNINGTON: Sorry, Bill. Do you</p> <p>3 have an extra copy?</p> <p>4 MR. COSTON: Oh, sorry.</p> <p>5 THE WITNESS: Yes, I can.</p> <p>6 BY MR. COSTON:</p> <p>7 Q. And what is it, please?</p> <p>8 A. Well, it's the expert report that I provided</p> <p>9 to the District Court for the District of Delaware in</p> <p>10 the case of Bavarian Nordic versus Acambis.</p> <p>11 Q. Other than the opinions that are expressed in</p> <p>12 this expert report, will you provide any other expert</p> <p>13 opinions in the Delaware litigation?</p> <p>14 A. I think at this point in time, no.</p> <p>15 Q. Let's -- let's go through the opinions then.</p> <p>16 In paragraph 3 it is stated: "I understand that BN</p> <p>17 claims that a specific biological material referenced</p> <p>18 to as MVA 572 has been unlawfully converted by Acambis,</p> <p>19 which I understand is one of the allegations of unfair</p> <p>20 trade practices raised against Acambis in this case."</p> <p>21 What is the basis for your understanding that</p> <p>22 BN claims that 572 was unlawfully converted by Acambis?</p>	<p style="text-align: right;">Page 8</p> <p>1 are what we call clonal isolates, and those were then</p> <p>2 provided to Acambis by the NIH. That particular</p> <p>3 procedure of plaque purification is standard practice</p> <p>4 in virology, but it doesn't -- I'm sorry. That's all</p> <p>5 I would like to say.</p> <p>6 Q. Right. You use the term clones or clonal</p> <p>7 isolates. Is -- were the clonal isolates sent by NIH</p> <p>8 on to Acambis genetically identical to the 572 that the</p> <p>9 NIH received from Mayr?</p> <p>10 MR. PENNINGTON: Objection, vague.</p> <p>11 BY MR. COSTON:</p> <p>12 Q. What do you mean by the term clonal isolate?</p> <p>13 A. The clonal isolate describes a procedure. A</p> <p>14 clonal isolate is a term that indicates the procedure</p> <p>15 one goes through to produce a clone of the virus.</p> <p>16 Q. Now, in layman's term, a clone means something</p> <p>17 identical?</p> <p>18 A. Exactly.</p> <p>19 Q. Is that how you're using the term clone?</p> <p>20 A. Yes. A clone is -- is single virus from --</p> <p>21 the purpose of cloning is to produce -- to pick out</p> <p>22 from a population a single virus particle that will</p>
<p style="text-align: right;">Page 7</p> <p>1 A. Well, I'll just express what's stated here in</p> <p>2 different words. The 572 virus was provided to --</p> <p>3 that is at debate in this case was provided by Anton</p> <p>4 Mayr, Dr. Anton Mayr, to the NIH, to the Laboratory of</p> <p>5 Viral Diseases at the NIH directed to Dr. Moss for</p> <p>6 conducting studies in the -- research studies in their</p> <p>7 laboratory.</p> <p>8 This particular virus or plaque purified</p> <p>9 viruses derived from this particular virus were then</p> <p>10 given to Acambis for commercial purposes, and Dr. Mayr</p> <p>11 has repeatedly stated, too, as well Bavarian Nordic</p> <p>12 have repeatedly pointed out the fact that use of</p> <p>13 that -- those viruses, the sending of those viruses</p> <p>14 to Dr. Moss's lab was only for research purposes and</p> <p>15 not for commercial use.</p> <p>16 Q. Let's break that down a little bit. You</p> <p>17 indicated that Moss sent 572 or viruses derived on to</p> <p>18 Acambis. What did you mean by viruses derived?</p> <p>19 A. At the NIH, the 572 virus was plaque purified,</p> <p>20 which means that there were clones that were picked,</p> <p>21 clonal isolates picked after putting the 572 virus on,</p> <p>22 I believe, chicken embryo fiberglass and these plaques</p>	<p style="text-align: right;">Page 9</p> <p>1 then grow up into a larger population and be derived</p> <p>2 from a single individual.</p> <p>3 Q. So that under your theory in this case on</p> <p>4 conversion, the conversion occurred because NIH sent</p> <p>5 Acambis a clone of what Mayr had sent the NIH?</p> <p>6 A. No, that's not exactly what I meant.</p> <p>7 Q. Did the NIH send Acambis --</p> <p>8 A. The NIH sent to Acambis essentially the 572</p> <p>9 virus. Virus that had been very straightforwardly</p> <p>10 derived from the 572 virus and which was bioequivalent,</p> <p>11 if you like, to the MVA 572 virus.</p> <p>12 Q. And by bioequivalent, what do you mean?</p> <p>13 A. That means that one would expect that the</p> <p>14 clones that were made -- the plaque purified clones</p> <p>15 that were made from MVA 572 would display essentially</p> <p>16 the same properties as MVA 572.</p> <p>17 Q. Now, in your early answer, when I said --</p> <p>18 asked you for the basis for your understanding, another</p> <p>19 comment you made was that Mayr sent the virus to the</p> <p>20 NIH I believe your statement was "for conducting</p> <p>21 research." What is the basis for your understanding</p> <p>22 that Mayr sent the virus to the NIH for conducting</p>

3 (Pages 6 to 9)

<p style="text-align: right;">Page 10</p> <p>1 research?</p> <p>2 A. Well, the NIH laboratory, Laboratory of Viral</p> <p>3 Diseases is a well-known laboratory in conducting</p> <p>4 research on pox viruses, many vaccinia virus, other pox</p> <p>5 viruses as well in also particular MVA but not only</p> <p>6 MVA, and that is basically my -- the reason why Anton</p> <p>7 Mayr would accept to send his virus to -- to that</p> <p>8 particular laboratory.</p> <p>9 Q. You're not aware of any writings between Mayr</p> <p>10 and Moss that explicitly said, this is for research</p> <p>11 purposes only?</p> <p>12 A. I'm aware of writing. No, I'm not aware.</p> <p>13 I'm aware -- sorry -- of writings. Could we start all</p> <p>14 over again, please?</p> <p>15 Q. Yeah.</p> <p>16 A. I'm aware of writings or letters exchanged</p> <p>17 between Bernard Moss and Anton Mayr that on the one</p> <p>18 hand, Bernard Moss requesting samples, on the other</p> <p>19 hands, Anton Mayr accepting to send him samples of his</p> <p>20 virus.</p> <p>21 Q. Of all the writings of which you are aware,</p> <p>22 are you aware of any that explicitly say, this is for</p>	<p style="text-align: right;">Page 12</p> <p>1 materials, but it was an understanding that that</p> <p>2 limitation would apply as there is this kind of</p> <p>3 understanding in the research community.</p> <p>4 Q. So, by saying that there was an understanding,</p> <p>5 what do you mean?</p> <p>6 A. An understanding that the material was</p> <p>7 provided for research purposes --</p> <p>8 Q. Is that --</p> <p>9 A. -- and that --</p> <p>10 Q. Is that the same as agreement?</p> <p>11 A. It's the same as an agreement, yes.</p> <p>12 Q. In your written expert report, I don't believe</p> <p>13 you comment on the question of whether the NIH under</p> <p>14 your theory would have had the right to provide MVA</p> <p>15 strain to others for research purposes. Do you have</p> <p>16 an opinion on that question?</p> <p>17 A. I think it would be appropriate for the NIH to</p> <p>18 request the -- the permission or the -- the permission</p> <p>19 of Anton Mayr to distribute that material for research</p> <p>20 purposes to other research institutions. Yes, it would</p> <p>21 be appropriate.</p> <p>22 Q. It would be appropriate to ask permission?</p>
<p style="text-align: right;">Page 11</p> <p>1 research purposes only?</p> <p>2 A. What I'm actually aware of is that it's</p> <p>3 customary practice to send the biologicals that was</p> <p>4 when is developed in one's laboratory to other</p> <p>5 laboratories interested in studying the particular</p> <p>6 biological one has created or developed or invented in</p> <p>7 different matters.</p> <p>8 Q. All right. So, to go back to my underlying</p> <p>9 question: Are you aware of any writing which</p> <p>10 explicitly said this MVA 572 is to be used for research</p> <p>11 purposes only, an explicit writing?</p> <p>12 A. I'd have to go back to the letters to look at</p> <p>13 them more carefully.</p> <p>14 Q. Do you have an opinion as to whether or not</p> <p>15 Mayr and Moss entered into an agreement that limited</p> <p>16 the use of the virus to research purposes only?</p> <p>17 A. Well, as I said previously, it's standard</p> <p>18 practice, customary practice between researchers to</p> <p>19 provide material to other researches for -- for</p> <p>20 fundamental studies. So I don't think this is an</p> <p>21 exception. It's many that was not necessarily</p> <p>22 written, a written limitation on the use of those</p>	<p style="text-align: right;">Page 13</p> <p>1 A. It would be appropriate. It --</p> <p>2 Q. Do you have an opinion --</p> <p>3 A. I think it depends a bit on the circumstances</p> <p>4 of distribution of the material. If the material was</p> <p>5 distributed in the context of collaborations, then that</p> <p>6 would not necessarily require a request for permission,</p> <p>7 but if it was distributed without in a -- in a</p> <p>8 situation where there was freedom to -- complete</p> <p>9 freedom to use the virus for research, I think it would</p> <p>10 be more appropriate to request permission of Anton</p> <p>11 Mayr.</p> <p>12 This is often standard practice to go to the</p> <p>13 original source. The standard practice to go to the</p> <p>14 original source of material to ask for the right to use</p> <p>15 that material even for research purposes. Although, I</p> <p>16 mean, there is often quite freedom of distribution</p> <p>17 among research laboratories without these requests</p> <p>18 being made. So practices are not always in conformity</p> <p>19 to -- to what should I'd say ethically be done, of</p> <p>20 course.</p> <p>21 Q. So, breaking that down a little bit, is it</p> <p>22 your opinion that if the NIH were collaborating with</p>

4 (Pages 10 to 13)

<p style="text-align: right;">Page 54</p> <p>1 A. There's some -- there's some legal content. 2 You know, the terms I'm not competent to say that is 3 the appropriate term, but, no, I don't think anything 4 wrong. 5 Q. Right. Let's go to paragraph 2 which 6 addresses Mayr's work at the Bavarian State Vaccine 7 Institute. There's a reference to two -- to a couple 8 of citations of a September 21 deposition of Anton 9 Mayr. You said you did read that deposition, correct? 10 A. Yes. 11 Q. And at least according to this, in his 12 deposition he said that while he was an employee of the 13 Bavarian State Vaccine Institute, "all material that I 14 worked with was the property of that institute." You 15 see that? 16 A. Yes. Well, that particular paragraph I'd like 17 to make a comment on. 18 Q. Sure. 19 A. I believe there's a confusion in Anton Mayr's 20 mind because he is clearly -- if one looks at his 21 references, it appears clear that MVA was developed 22 from the late, very late '50s, maybe '58, '59 up to</p>	<p style="text-align: right;">Page 56</p> <p>1 yes, and the use of MVA as an inducer of power 2 immunity. 3 Q. Have you reviewed those patents? Looked at 4 them? 5 A. I'm aware of, I mean, the scientific basis of 6 those patents. I haven't looked in any detail at the 7 description in those patents, but I'm aware of the 8 scientific articles that were associated with those 9 patents. 10 Q. Have you read the patents themselves? 11 A. No. 12 Q. In paragraph 3, the last sentence says, "Mayr 13 testified that he 'worked with this strain at the 14 Bavarian Vaccination Institute' and I worked there as 15 an employee. All material that I worked with was the 16 property of that institute." 17 In reading the deposition, what understanding, 18 if any, did you come to with respect to what he meant 19 by this strain? 20 A. Okay. I'll read the paragraph and then answer 21 your question. 22 Q. Yeah, that's fine. Okay.</p>
<p style="text-align: right;">Page 55</p> <p>1 1974 and, of course, the actual MVA 516 I believe when 2 it first was called MVA goes back to the '60s because 3 you need to do a certain number of passages. It takes 4 a certain number of times to get up to 516 and, 5 therefore, the sentence "All material that I worked 6 with was the property of that institute," during the 7 period of time where he was Bavarian State Vaccine 8 Institute, he was not working with MVA. 9 So this sentence cannot -- this comment cannot 10 refer to MVA. Because during that period of time, he 11 was not conducting research on MVA or he did not -- he 12 was not in the process of making an MVA virus. 13 Q. So that when Mayr -- your belief is that Mayr 14 was mistaken in his deposition? 15 A. Well, the sentence doesn't actually say what 16 he was referring to. So he may have been referring to 17 the material that he was working with at the time, 18 which was not MVA. 19 Q. Are you aware of any patents that were applied 20 for in the name of the Free State of Bavaria concerning 21 MVA? 22 A. Yeah. Well, I know there were a few patents,</p>	<p style="text-align: right;">Page 57</p> <p>1 A. I guess he's referring to the strain CVA that 2 he obtained from Ankara, Turkey. 3 Q. So that you read his deposition as saying that 4 the Bavarian Vaccination Institute was the owner of the 5 CVA virus, not MVA virus? 6 A. No, I don't. I mean the CVA virus was -- I 7 mean, there's not necessarily ownership in the area of 8 Smallpox vaccines in the sense that those vaccines go 9 back to Edward Jenner's time in the late 1700s, and 10 those are actually -- those are very, very old strains 11 in the scientific community at large. Belonging to 12 the scientific community at large. 13 Q. Is it important to you in forming your opinion 14 on conversion to know whether or not Mayr was the owner 15 of MVA 572? 16 MR. PENNINGTON: Objection, vague. 17 THE WITNESS: If that had been somebody 18 else than Mayr, I think the problem would be the same 19 in the sense that if a biological provided by a 20 scientist, whoever it is, is used by industry for 21 making a commercial product, then it appears to me to 22 be the proper fashion to go about this. That industry</p>

15 (Pages 54 to 57)

<p style="text-align: right;">Page 58</p> <p>1 would refer to the source of that material and decided</p> <p>2 to enter into an agreement of some sort with the owner,</p> <p>3 whoever it is, be it Mayr or somebody else of that</p> <p>4 material.</p> <p>5 BY MR. COSTON:</p> <p>6 Q. Let me see if I can break that down a little</p> <p>7 bit. If Mayr had given out CVA rather than MVA, would</p> <p>8 you still have the same opinion; that is, that his</p> <p>9 provision of CVA to the NIH was only for research</p> <p>10 purposes?</p> <p>11 A. Well, as I think I said previously that in the</p> <p>12 area of Smallpox vaccines, which go back to the late</p> <p>13 1700s, there is no problem of ownership of property.</p> <p>14 No problem of ownership of property of those of those</p> <p>15 vaccines. They are given. The time that has gone</p> <p>16 by, they are in the public domain. So that -- so</p> <p>17 there would not be a problem in distribution of CVA as</p> <p>18 far as concerns industrial use of that particular</p> <p>19 strain.</p> <p>20 Q. Is it your opinion that once a virus is in the</p> <p>21 public domain that anyone is free to use it either for</p> <p>22 research purposes or for commercial purposes?</p>	<p style="text-align: right;">Page 60</p> <p>1 CVA. Do we agree that's in the public domain?</p> <p>2 A. Yes, I believe so.</p> <p>3 Q. And if each one of the five of us in this room</p> <p>4 have a clone of CVA, we all have the same virus,</p> <p>5 correct?</p> <p>6 A. Well, funny enough, there's a little bit of</p> <p>7 debate even about that that I'm not qualified to answer</p> <p>8 your question, and it turns out that Acambis has cloned</p> <p>9 a virus in the public domain, which is Trivax, and</p> <p>10 they've taken out a patent on it and so now they</p> <p>11 somehow have covered the use of a virus that was in the</p> <p>12 public domain simply by cloning it.</p> <p>13 So it's a technical question. Is this -- do</p> <p>14 they have a legal right to do that or, you know, would</p> <p>15 someone try to say they don't have it or they do or are</p> <p>16 they supported? I really don't have the answer to</p> <p>17 that question. It's a complex question. I think</p> <p>18 it's out of the scope of my abilities.</p> <p>19 Q. Well, I'm going to circle back to whether it's</p> <p>20 within your area of competence or not, but with respect</p> <p>21 to the Acambis patent, is that the patent that came up</p> <p>22 in the ITC case that Dr. Monath was asked about?</p>
<p style="text-align: right;">Page 59</p> <p>1 A. Yes, but I think, you know, I think that the</p> <p>2 problem lies with the definition of what public domain</p> <p>3 is, which is, of course, a term which a legal -- people</p> <p>4 legally qualified can do much better than I.</p> <p>5 Q. Following through with that opinion, if MVA</p> <p>6 572 were in the public domain, anyone would be free to</p> <p>7 use it for commercial or research purposes?</p> <p>8 MR. PENNINGTON: Objection, vague.</p> <p>9 THE WITNESS: Again, I think that's -- I</p> <p>10 mean, obviously this is the debate in this matter. So</p> <p>11 if it's in the public domain, you're better qualified</p> <p>12 than me to say if it's free of use for research -- for</p> <p>13 industrial purposes. You're much better qualified to</p> <p>14 answer that particular question, but my tendency would</p> <p>15 be to say yes, but without the proper qualifications.</p> <p>16 BY MR. COSTON:</p> <p>17 Q. I guess what I'm getting at here is, because</p> <p>18 these viruses -- because you can make clones of</p> <p>19 viruses, right?</p> <p>20 A. (Nods head).</p> <p>21 Q. Everybody in this room might have -- let's</p> <p>22 take a virus that we accept as in the public domain.</p>	<p style="text-align: right;">Page 61</p> <p>1 A. Yes, I believe he was asked about that.</p> <p>2 Well, I believe it came up at one point, yes.</p> <p>3 Q. Do you recall that he testified that Acambis</p> <p>4 has never asserted the patent against anyone for</p> <p>5 defensive purposes?</p> <p>6 A. That particular patent hasn't been attacked,</p> <p>7 yes, hasn't been questioned by anyone so far, yes.</p> <p>8 Q. And they haven't asserted it against anyone,</p> <p>9 to the best of your knowledge?</p> <p>10 A. Well, they haven't had to assert it, yes. If</p> <p>11 nobody makes -- objects to that particular patent, they</p> <p>12 don't have to assert it, do they? As far as I know,</p> <p>13 nobody has objected to that patent.</p> <p>14 Q. All right. Now, to go back to your</p> <p>15 competence in forming an opinion, what I was trying to</p> <p>16 get at with the hypothetical -- if we all have clones</p> <p>17 of a virus and let's say they're identical clones, and</p> <p>18 the virus is in the public domain, one might take a</p> <p>19 position that if I send my clone to the NIH, an</p> <p>20 aggressive position would be that the NIH can't send</p> <p>21 that off to someone else for commercial purposes</p> <p>22 because it's a piece of property that I owned and I</p>

16 (Pages 58 to 61)

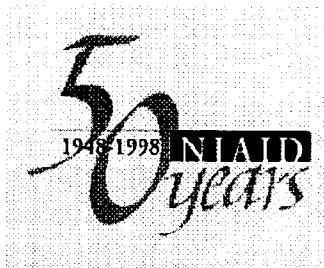
<p style="text-align: right;">Page 62</p> <p>1 gave to them.</p> <p>2 And I'm trying to get at your opinion whether</p> <p>3 if what I own -- and all five of us in the room have</p> <p>4 the identical virus as in the public domain, is anyone</p> <p>5 free to use it commercially, even though I was the -- I</p> <p>6 had physical custody of one of the five exact clones?</p> <p>7 MR. PENNINGTON: Objection, vague and</p> <p>8 foundation.</p> <p>9 BY MR. COSTON:</p> <p>10 Q. World's longest question. But you can answer</p> <p>11 if you can.</p> <p>12 A. Well, I think we're confusing two issues.</p> <p>13 Q. Okay. What have I confused?</p> <p>14 A. Well, the -- we're confusing the issue of the</p> <p>15 notion of property of biological owner and the</p> <p>16 potential property -- the intellectual property</p> <p>17 knowledge of a particular clone, but this is -- again,</p> <p>18 this is an area where you're much more competent than I</p> <p>19 am. I mean, I'm willing to give an opinion, but the</p> <p>20 opinion I have is not, you know, based on legal</p> <p>21 knowledge.</p> <p>22 Q. All right. Leaving aside the legal</p>	<p style="text-align: right;">Page 64</p> <p>1 BY MR. COSTON:</p> <p>2 Q. Well, I think it's --</p> <p>3 A. Again, I really am not qualified to answer</p> <p>4 those questions. They are very legally technically</p> <p>5 oriented -- very technically oriented legally. I</p> <p>6 mean, I don't think my answer has much value to --</p> <p>7 because I'm not a specialist in the legal aspects of</p> <p>8 this issue. I mean, I can testify and I can give you</p> <p>9 some opinions on what the -- how scientists practice</p> <p>10 the distribution of their materials and what they</p> <p>11 expect when they distribute materials to industry.</p> <p>12 Q. Well, then let me ask it that way. From the</p> <p>13 view of someone who's a scientist in the industry, if</p> <p>14 you received a clone of a virus that was in the public</p> <p>15 domain?</p> <p>16 A. As a scientist?</p> <p>17 Q. Yeah. As a scientist, would you feel that you</p> <p>18 had the right to clone that and send it on to</p> <p>19 commercial entities?</p> <p>20 A. Yes. Yes.</p> <p>21 Q. In preparing your expert opinion in this case,</p> <p>22 what efforts, if any, did you take to determine whether</p>
<p style="text-align: right;">Page 63</p> <p>1 knowledge, I will take your answer. What is your</p> <p>2 opinion on that as a member of the community of</p> <p>3 virologists? If it's a public domain virus, could one</p> <p>4 still claim some property interest in that particular</p> <p>5 clone that one had physical possession of and block</p> <p>6 commercial exploitation by a recipient of that clone?</p> <p>7 A. Well --</p> <p>8 MR. PENNINGTON: Same objections by the</p> <p>9 way.</p> <p>10 THE WITNESS: Well, the property</p> <p>11 interest, of course, exists because it's in -- one has</p> <p>12 the ownership of the clone if it's in one's laboratory.</p> <p>13 So there's no obligation to distribute that ownership.</p> <p>14 BY MR. COSTON:</p> <p>15 Q. Once I have distributed a copy of my clone, I</p> <p>16 clone my clone and send my clone to the NIH?</p> <p>17 A. Uh-huh.</p> <p>18 Q. Again, assuming this is a public domain virus,</p> <p>19 is the NIH free to make copies and distribute their</p> <p>20 copies for commercial use?</p> <p>21 MR. PENNINGTON: Objection, vague and</p> <p>22 foundation. And outside the scope of his report.</p>	<p style="text-align: right;">Page 65</p> <p>1 Mayr was the owner of MVA 572?</p> <p>2 A. Well, I was aware before this case had</p> <p>3 actually begun from the literature and from how -- how</p> <p>4 other scientists viewed this area, how I myself viewed</p> <p>5 this area, that Mayr was the owner of the MVA strains</p> <p>6 that he had been distributing over many, many years.</p> <p>7 Anton Mayr created the virus in his lab. Over a long</p> <p>8 period of time, he defined the properties of this</p> <p>9 virus.</p> <p>10 He made it available to the research community</p> <p>11 to continue studying the properties of the virus and</p> <p>12 maybe make other uses of the virus that they could</p> <p>13 imagine, and he was constantly contacted by many</p> <p>14 different researchers to -- who wished to use his</p> <p>15 virus. So he was recognized by all scientists in the</p> <p>16 field as the owner, the creator of the virus, the owner</p> <p>17 as well as by myself as the creator and owner of this</p> <p>18 virus.</p> <p>19 Q. In preparing your expert report, what efforts,</p> <p>20 if any, did you make to look into what rights, if any,</p> <p>21 the Bavarian Vaccine Institute may have had to MVA 572?</p> <p>22 A. Well, my impression is that the work that</p>

17 (Pages 62 to 65)

<p style="text-align: right;">Page 82</p> <p>1 like.</p> <p>2 Q. On the second point, the transfer point, your</p> <p>3 answer made reference to something called "proper</p> <p>4 conduct." What did you mean by proper conduct?</p> <p>5 A. Well, my feeling is that the -- it's unlawful</p> <p>6 to use a biological obtained from a researcher without</p> <p>7 first entering into an agreement with this researcher</p> <p>8 for obtaining the right to use it and some sort of</p> <p>9 agreement which will compensate the researcher for the</p> <p>10 effort he has made in making the product and making the</p> <p>11 particular discovery he has made.</p> <p>12 Q. Based on the record that you've seen, do you</p> <p>13 think that Mayr and NIH had an agreement that NIH would</p> <p>14 not allow commercial exploitation of the virus?</p> <p>15 A. Based on the documentation, I think there was</p> <p>16 -- there was an understanding that MVA could be used</p> <p>17 freely for research purposes and I think that, you</p> <p>18 know, up to the -- there was for many years no -- no</p> <p>19 notion that that would become, of course, a product;</p> <p>20 but if in the case that became a product, then it would</p> <p>21 be only natural for whoever would make a product of it</p> <p>22 to go back and -- and get allowance to get</p>	<p style="text-align: right;">Page 84</p> <p>1 exploitation?</p> <p>2 MR. PENNINGTON: Same objection.</p> <p>3 THE WITNESS: Well, again, it's an</p> <p>4 agreement that there would not be commercial</p> <p>5 exploitation before, you know, having a second</p> <p>6 agreement that there is commercial exploitation. It</p> <p>7 didn't exclude at one point there would be commercial</p> <p>8 exploitation, provided that a second round of</p> <p>9 discussions would occur with a person who provided the</p> <p>10 initial sample.</p> <p>11 BY MR. COSTON:</p> <p>12 Q. Paragraph --</p> <p>13 A. I mean, I think --</p> <p>14 Q. Go ahead.</p> <p>15 A. No, no. I'm sorry.</p> <p>16 Q. Paragraph 49 of the complaint uses the</p> <p>17 language of agreement, and I'm asking you as a person</p> <p>18 who's giving an opinion on conversion whether or not as</p> <p>19 a member of the scientific community, you believe that</p> <p>20 there was in fact an agreement between Mayr and the NIH</p> <p>21 that it would be limited to research purposes only.</p> <p>22 A. Well, not only -- well, not only do I believe</p>
<p style="text-align: right;">Page 83</p> <p>1 authorization to do that.</p> <p>2 Q. Let me direct your attention to paragraph 49</p> <p>3 of the first amended complaint in this case, which</p> <p>4 states: "Acambis had no right to possess MVA 572</p> <p>5 and/or its progeny received from NIH because any</p> <p>6 delivery to Acambis of MVA 572 or its progeny violated</p> <p>7 the agreement with Professor Mayr." You see that?</p> <p>8 A. Yes.</p> <p>9 Q. In the course of preparing your expert report,</p> <p>10 have you come to an opinion on whether or not there in</p> <p>11 fact was an agreement between Mayr and the NIH?</p> <p>12 MR. PENNINGTON: Objection, asked and</p> <p>13 answered.</p> <p>14 BY MR. COSTON:</p> <p>15 Q. Please answer.</p> <p>16 A. Well, I think Mayr explicitly at one point in</p> <p>17 time, or maybe at several points in time, mentioned the</p> <p>18 fact that he had transmitted the virus to the NIH for</p> <p>19 research purposes.</p> <p>20 Q. And my question is: In the scientific</p> <p>21 community, would you understand that to be an agreement</p> <p>22 with NIH that there would not be commercial</p>	<p style="text-align: right;">Page 85</p> <p>1 that, but I think the NIH believed that as well at one</p> <p>2 point. That they could not distribute MVA, the sample,</p> <p>3 they could not distribute MVA samples that they had</p> <p>4 derived from the MVA they received from Anton Mayr.</p> <p>5 That they could not distribute it to other laboratories</p> <p>6 since they -- I think there are documents that confirm</p> <p>7 that, that show that the NIH in the person of Bernie</p> <p>8 Moss expressed the view that he had -- that one should</p> <p>9 consult, one should ask permission of Anton Mayr before</p> <p>10 sending out those samples to other labs than his own.</p> <p>11 So there was a change. Clearly there was a</p> <p>12 change in opinion at the NIH, but the earlier opinion,</p> <p>13 in my view, is the correct opinion and is the one that</p> <p>14 is shared by the research community at large.</p> <p>15 Q. Now, have you read the deposition of a Therion</p> <p>16 representative, a woman named I believe it's Linda</p> <p>17 Gritz?</p> <p>18 A. Yes.</p> <p>19 Q. Have you read the transcript of that?</p> <p>20 A. I've read portions of it.</p> <p>21 Q. Did you read the portion where she recounted a</p> <p>22 telephone conversation she'd had with Anton Mayr?</p>

22 (Pages 82 to 85)

EXHIBIT 32



OMB No. 0990-0115

Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE <http://www.niaid.nih.gov/contract/default.htm> FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended. NOTE: The issuance of this solicitation does not commit the government to an award.				
RFP Number: NIH-NIAID-DMID-03-44	Just In Time: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Small Bus. Set-Aside <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 8(a) Set-Aside <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No NAICS Code 541710 Size Standard 500 employees	Level of Effort: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Total Effort: <input type="checkbox"/> N/A <input checked="" type="checkbox"/>	
TITLE: <p style="text-align: center;">Development and Testing of a Modified Vaccinia Ankara (MVA) Vaccine</p>				
Issue Date: August 15, 2002	Due Date: September 30, 2002 Time: 4:00 PM, EST	Technical Proposal Page Limits: <input type="checkbox"/> Yes (see "How to Prepare and Submit Electronic Proposals") <input checked="" type="checkbox"/> No		
ISSUED BY: Jacqueline C. Holden Contracting Officer Contract Management Branch, DEA NIH, NIAID 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, MD 20892-7612		<input type="checkbox"/> <i>We reserve the right to make awards without discussion.</i>		
		NO. OF AWARDS: <input type="checkbox"/> Only 1 Award <input checked="" type="checkbox"/> Multiple Awards	PERIOD OF PERFORMANCE: Part A: 3 years beginning on or about 01/31/2003 Part B, Option: Up to 24 Months	
Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)				
The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.				
POINT OF CONTACT -- Phil Hastings --COLLECT CALLS WILL NOT BE ACCEPTED--				
Telephone: Direct 301-496-0194 Main 301-496-0612		Fax 301-402-0972		E-Mail ph23k@nih.gov

Updated thru FAC 2001-07 (05/15/02)

C. ANENOV
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SECTION M -- EVALUATION FACTORS FOR AWARD

PLEASE NOTE: If you intend to submit a proposal in response to this RFP, you are requested to submit a PROPOSAL INTENT RESPONSE SHEET by **Monday, September 9, 2002**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

BACKGROUND / STATEMENT OF WORK / NOTES TO OFFERORS**Background****Development and Testing of a Modified Vaccinia Ankara (MVA) Vaccine
RFP NIH-NIAID-DMID-03-44**

The National Institute of Allergy and Infectious Diseases (NIAID) is the primary institute at the National Institutes of Health (NIH) for emerging infectious disease research, including research on pathogens that can be used as agents of bioterrorism. Bioterrorism is defined as the use of microorganisms that cause human disease, or the toxins released from them, to harm people or elicit widespread fear or intimidation of society.

The events of the past year have significantly changed the world's perception of the nature and degree of the threats posed by the use of infectious agents as weapons of bioterrorism. The risk of using such weapons once appeared to be restricted to military encounters. However, the deliberate exposure of postal workers, other government employees and the American public at large to *Bacillus anthracis* spores highlighted the need to devise appropriate and effective measures to protect all U.S. citizens from the harmful effects of those biologic agents of most concern.

Smallpox is an infectious disease caused by the variola virus, a member of the orthopox family. The global eradication of smallpox in 1980 has been heralded as one of the most significant feats of mankind. In 1971, the last case of smallpox in the Americas was seen. Shortly thereafter, routine smallpox immunization was discontinued in the U.S. because the risk of vaccination outweighed the threat of the disease. Recent knowledge on the weaponization and availability of smallpox stocks to rogue nations has increased concern about the population's vulnerability to this disease. As a result of this assessment, the U.S. government is currently procuring enough smallpox vaccine for every U.S. citizen.

The vaccine that contributed to the eradication of smallpox was based on a live, replicating vaccinia virus that had been attenuated over time through serial passages in tissue culture. This vaccine is reactogenic, causing common side effects such as redness and swelling at the site of vaccination, fever, or muscle aches in over 90% of people. Although rare in healthy recipients of the vaccine, vaccination with vaccinia can cause encephalitis, eczema vaccinatum, disseminated vaccinia and even death. The frequency of these events is increased as the ability to control the vaccinia replication is decreased such as when a person's immune system becomes increasingly compromised. The number of U.S. citizens at risk for these rare events has increased over the years due to life-saving drugs and medical procedures which compromise the immune system such as those drugs administered following organ transplant and the increased number of cases of HIV-infection. This fact has raised concerns about the wisdom of vaccinating every U.S. citizen with live, replicating vaccinia vaccine, should that need arise.

Modified Vaccinia Ankara (MVA) is a strain of vaccinia that has been further attenuated by serial passage in chick embryo fibroblasts. MVA has a substantial clinical history due to its extensive use as a vaccine to immunize over 120,000 people during the smallpox mass vaccination campaign in Germany in the 1970's. In most human and primate cells, replication of the virus is blocked at the final stages of maturation, but most of the viral proteins are produced. Very limited replication (less than two plaque forming unit/cell) is seen in some mammalian cell lines. The gene deletions (approximately 33kbp) associated with MVA have been partially characterized. At least two host range genes are absent, as are the genes associated with at least four immunomodulatory proteins. Both neutralizing and hemagglutination inhibition antibodies are, however, produced. There is also some evidence that MVA can protect against variola virus challenge in monkeys. Most recently tested as an experimental vaccine vector for the delivery of other vaccine candidates, including HIV and cancer vaccines, the safety profile has been expanded to include contemporary data in recipients with potential immunocompromised status.

To address the urgent and compelling need to accelerate the development and stockpiling of MVA smallpox vaccines, the government has developed a comprehensive approach that includes both collaborative opportunities with NIAID as well as contract awards. Collaborative opportunities are not the subject of this Request for Proposals (RFP), however it is briefly described here for the sake of completeness. Collaborative opportunities from NIAID are available to all legitimate parties and include: the availability of a master seed stock of MVA from NIAID; the availability of some characterized reagents and standard operating procedures (SOPs) for immunologic measurements; assistance in evaluating Investigational New Drug (IND) grade vaccine candidates in relevant animal models; and assistance with testing of IND vaccine candidates in clinical trials through the NIAID clinical trials contract network. Further information regarding the requirements for requesting collaborative opportunities is described below.

It is the intent of the Government to provide contract support for the development and stockpiling of MVA vaccines through the issuance of three sequential Request for Proposals (RFPs). The first procurement action and the subject of this RFP (NIAID-DMID-03-44) is intended to provide resources for the initial development of MVA vaccine candidates. In addition, the Government intends to issue a second RFP during the summer of 2003, entitled "Production and Acquisition of MVA Vaccine." The objective of the second RFP will be to manufacture, formulate, fill and finish, and test, in accordance with cGMP regulations, up to 30 million doses of MVA vaccine to constitute the U.S. Government's stockpile for emergency use under IND, and to provide a licensure plan to include the conduct of expanded human safety studies required for licensure and the conduct of pivotal animal protection studies. A third contract action for the acquisition of a licensed product is being planned for 2005, under the auspices of the Centers for Disease Control (CDC).

Participation in NIAID's initial RFP (NIAID-DMID 03-44) will not be a pre-requisite for participation in subsequent MVA vaccine procurements planned by the NIAID and the CDC.

**Information Required to Request
Consideration for NIAID Collaborative Opportunities**

1. Evidence that the offeror/requestor/interested party has secured access to all intellectual property, know-how and tangible materials for this proposed work, or has a plan to secure such intellectual property, know-how and tangible materials.
2. Characterization data for the vaccine candidate that demonstrates manufacturing, control and safety features. Data should include, but not be limited to, the following:
 - a. Chemistry, manufacturing and control testing information to include:
 - i. Documentation of all raw materials used in the production of the master and working seed viruses and any cell substrates used in the production of the vaccine. All animal derived materials used in the production of the master seeds or cell banks as well as the manufacturing of the vaccine should be described and the country of origin of the animals should also be provided. Tabular form is requested.
 - ii. Description of the production of the seed virus and cell banks used in vaccine production. Inclusion of a flow diagram is requested.
3. Description of vaccine production. Inclusion of a flow diagram is requested.
4. Summary of all process and release testing and the respective data to assess purity, potency, and safety of the product.
5. Data to support the stability and consistency of manufacturing. Examples of the type of stability for MVA includes demonstration of the stability of the genotype and phenotype and inclusion of a complete evaluation of the non-replicative/or limited replication of the vaccine candidate in multiple mammalian cell lines.
6. Pre-clinical safety data to include:
 - a. Data demonstrating the safety of the candidate vaccine as well as the design of the preclinical studies used in the assessment.
 - b. Data to support the lack of/or limited replication in animals and the stability of the genetic phenotype.
7. Documentation that the vaccine candidate can elicit an immune response in animals. Rationale for the choice of the animal model used and the regimen evaluated should also be included.
8. All animal data evaluating vaccine dosage and immunization regimens.
9. Any additional pre-clinical data to demonstrate "proof of concept", effectiveness. Protocols should also be included.

For more information regarding collaborative opportunities with NIAID, please contact Deborah Katz of the Office of Biodefense Research Affairs, DMID/NIAID, at dkatz@niaid.nih.gov.

Statement of Work – PART A
Development and Testing of a Modified Vaccinia Ankara (MVA) Vaccine
RFP NIH-NIAID-DMID-03-44

Introduction

This RFP (NIH-NIAID-DMID-03-44), for the initial development of MVA vaccine candidates, consists of 2 parts. Part A addresses development, manufacturing, testing and the conduct of Phase I studies in healthy populations. Specifically, the main objectives of Part A are to:

- Develop an MVA vaccine. This will include the development of the product as well as preparation of the chemistry, manufacturing and control (CMC) data to support use of this product under an IND application submitted to the Food and Drug Administration (FDA).
- Assess protection and immunogenicity provided by MVA vaccines in appropriate animal models.
- Conduct Phase I clinical trials to assess the safety and immunogenicity of MVA candidate vaccines.
- Develop a feasibility plan to manufacture and fill at least 30 million doses of MVA vaccine under current Good Manufacturing Processes (cGMP). This plan will include product characterization and product release and stability testing. The plan will also include production and testing of diluents, preservatives and other final ingredients that may be required.

Part B is an option to this contract requirement and, if exercised by the Government, will provide for the conduct of expanded Phase II clinical studies in healthy populations (i.e., adults and children) and Phase I and II studies in “at risk” (i.e., immunocompromised) populations.

Offerors must submit proposals for both Part A and Part B. For Part A, multiple awards may be made. For the Part B option, if exercised, the Government will select the candidate vaccine(s) that meet the milestones outlined in the Statement of Work and show the best potential of being a successful MVA vaccine candidate. Contract(s) awarded under this RFP will be milestone and product driven. Therefore, following each milestone and the subsequent review by NIAID staff, down-selection (i.e., discontinuation of contract support by means of early contract termination) may occur based on the quality of products, results of pre-clinical testing, or if Statement of Work milestones are not met.

The U.S. Government has determined that the urgent nature of the current threat requires an accelerated pace of development, testing, approval and procurement of an emergency stockpile of this vaccine. Although future smallpox vaccines may be derived from other strains, formulated in a different manner, or based on another platform these novel approaches are not being considered for this solicitation due to the urgent need.

Statement of Work – Part A

Independently, and not as an agent of the government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the work described below.

This procurement will be milestone-driven and awarded in phases. Periodic assessments of progress and continuation of subsequent milestones will be based on timeliness and quality of deliverables and consultations between the contractor and NIAID program staff. **Cost proposals must be prepared based on the estimated cost of each milestone.**

- A. Using technology known to be acceptable in the production of vaccines licensed for use in the U.S., develop a prototype MVA vaccine that will protect against challenge in relevant animal models.

1. Milestone 1: Within three months of award, produce a bulk pilot lot (to support at least 5000 clinical doses) of prototype MVA vaccine, in a formulation that represents the process to be scaled up for subsequent large-scale production. This lot of vaccine is to be produced under manufacturing conditions necessary to support the use of this product under IND and future large-scale manufacturing. *(See Note #1 to Offeror.)*
2. Milestone 2: Within six months of award of Part A, provide the NIH with 5000 doses of the final vaccine prototype, filled, finished and released as single dose vials and all information and authorization necessary to enable the government to file an IND for Phase I clinical trials, excluding only that considered to be proprietary, which may be summarized for NIAID and submitted to the FDA in a separate master file. *(See Note #2 to Offeror.)*
3. Milestone 3: Within six months of award, assess the protection and immunogenicity provided by MVA vaccine prototypes in appropriate animal models according to protocols approved by NIAID. *(See Note #3 to Offeror.)*
4. Milestone 4: Within 6 months of award, develop and submit for review and approval to NIAID, a clinical development plan for the evaluation of the vaccine, including protocols for the conduct of Phase I clinical trials (Part A), including the core Phase I requirements described in Attachment I, and protocols for the conduct of Part B optional clinical trials. To facilitate comparison of immunological and safety data currently being derived from ongoing studies of vaccinia, the NIAID will oversee the development of standardized Phase I (Part A) and Part B protocols in order to achieve consensus from all collaborating and participating parties.

For clinical trials conducted by the contractor under their own IND, the plan must provide information about the contract research organization (CRO) proposed to conduct the trials, including information about clinical personnel, laboratory procedures, proposed sites and timelines for their completion. The plan should describe the operational procedures the company will follow to assure adequate oversight of clinical trials, timely and accurate reporting of information to the FDA, structure and responsibilities of a data and safety monitoring board, as well as policies of how data will be processed, shared and published. The plan should specify how NIAID would be kept apprised of progress and communications with the FDA, including processes to assure NIAID may co-monitor or provide for independent audit of the clinical trial.

The Government, acting through the NIH, will facilitate attaining necessary resources to ensure that immunological assays from samples obtained in Phase I and Part B trials are evaluated using standardized assays that are currently being characterized and validated.

5. Milestone 5: Upon NIAID approval of the Phase I protocol, the contractor shall initiate Phase I trials. Standardized protocols, central laboratories and characterized reagents shall be used for neutralization and ELISA assays in all human trials.
6. Milestone 6: Within 12 months of the award, provide a feasibility plan to manufacture, formulate, fill and finish, test, and deliver to the Government up to 30 million doses of the candidate MVA vaccine suitable for storage in a stockpile for emergency use. The plan should include proposed steps to be taken to monitor the quality (e.g., stability testing plan) and to replenish the stockpile as needed to maintain its ready availability for emergency use under IND, as well as address the product development path for licensure. Accordingly, manufacturing plans should be designed for manufacture of licensed vaccine, not for retention of the vaccine in an IND status.

The feasibility plan shall include:

- a. Details of the process to scale-up production, including data to support the approach, i.e., documentation of successful scale-up of similar product class or data from intermediate scales of production;
- b. Timeline for production and delivery of up to 30 million doses of product;
- c. Strategy that will be pursued to seek a U.S. license for the product and to provide continued support for maintaining an active Government-held IND; to include obtaining expanded safety and immunogenicity data in all populations and the plan to meet the requirements of the Animal Efficacy Rule;
- d. Estimate of the cost/dose of up to 30 million doses delivered to the Government for use; and
- e. Plan to monitor (stability testing) and replenish the stockpile as needed in consultation with the managers of the Government stockpile. *(See Note #4 to Offeror.)*

7. Milestone 7: Within 15 months of award, complete an interim clinical trial report that includes data summary, data analysis and interpretation and conclusions for the Phase I trial. These data may be used by the Government and/or the contractor for consultations with the FDA concerning planning for subsequent product development and clinical trials.
 8. Milestone 8: Within 30 months of award, complete Phase I clinical trials and provide a report that captures all Phase I clinical trial follow-up and duration of immunity data. The report will include data summary, analysis and interpretation as well as final conclusions and recommendations.
- B. Meetings and Conferences - The Contractor shall participate in regular meetings to coordinate and direct the contract efforts as directed by the NIAID Project Officer. Such meetings may include, but are not limited to, meetings of all contractors to discuss clinical protocol design; meetings with individual contractors and other PHS officials to discuss technical, regulatory and ethical aspects of the program, and meetings with NIH technical consultants to discuss down-selection criteria and technical data provided by the contractor. *(See Note #5 to Offeror.)*

[END OF STATEMENT OF WORK – PART A]

EXHIBIT 33

$\Delta \pi$ EXHIBIT 187	
Deponent	
Date 2/9/06	Rptr. DV
www.deponet.com	

EXHIBIT #
RX-423C:1-4

From: Michael Mowatt [MMOWATT@niaid.nih.gov]
Sent: Tuesday, May 28, 2002 4:04 PM
To: 'Peter Wulff'
Subject: RE: 8 Apr 2002 facsimile to Dr. B. Moss

Peter,

I write to confirm my receipt last week of your letter, dated 13 May 2002, and the enclosures, which include 1) your 9 Apr 2002 facsimile transmittal to Dr. L. Gritz (Therion), on which Drs. B. Moss and A. Mayr received courtesy copies, 2) Dr. Gritz's 10 Jan 2002 letter to Dr. Mayr, and 3) Dr. Gritz's 26 Feb 2002 letter to Dr. Mayr. Thank you very much for supplying these documents.

As I mentioned in my electronic mail message of 10 May (below) I have found no evidence of the "stringent" material transfer agreement you mentioned during our conversation on 19 April. Instead, our records pertinent to the transfer of the MVA stock from Dr. Mayr to NIAID include only Dr. Mayr's 12 September 2001 letter to Dr. Moss. Likewise, I have found no evidence of an agreement between NIAID and Bavarian Nordic that relates to or would limit in any way NIAID's use or distribution of the MVA stock supplied by Dr. Mayr. Accordingly, since you have supplied no documentation to the contrary and in light of the pressing worldwide public health need I mentioned previously, NIAID will continue its vaccine research and development activities as planned.

Again, on behalf of the National Institute of Allergy and Infectious Diseases I would like to express my sincere appreciation of your assistance with this matter. Please let me know if you have any questions or if I can assist you further.

Regards,

Michael

-----Original Message-----

From: Peter Wulff [mailto:pw@Bavarian-Nordic.dk]
Sent: Friday, May 10, 2002 9:21 AM
To: 'Michael Mowatt'; Peter Wulff
Subject: RE: 8 Apr 2002 facsimile to Dr. B. Moss

Dear Michael Mowatt,

I am very sorry that I have not attended to this matter. I have been travelling a lot the last few weeks. I shall send the letter copies from Therion Monday. My secretary has left for today.

Best regards

Peter Wulff

-----Original Message-----

From: Michael Mowatt [mailto:MMOWATT@niaid.nih.gov]
Sent: 8. maj 2002 22:05
To: 'Peter Wulff'
Subject: RE: 8 Apr 2002 facsimile to Dr. B. Moss

Importance: High

Peter,

I write to confirm that I have not yet received from you the documents we discussed on 19 April and which I listed in my 24 April message (below) to you. However, since we last spoke on 19 April I have had an opportunity to gather information and documentation relevant to our discussion.

During our conversation you mentioned that Dr. Mayr provided the material to Dr. Moss under a "stringent" material transfer agreement. I have been unable to locate such an agreement. Instead, according to our records Dr. Mayr provided the material, "MVA 572.FHE - 22.02.1974," under cover of a letter, dated 12 September 2001, that describes the passage history of the lyophilized virus stock that he supplied to Dr. Moss. The letter specifies no limitations on NIAID's use of the materials. We understand that Dr. Mayr had full authority to transfer the material to NIAID. Your suggestion during our 19 April conversation that Bavarian Nordic negotiated an exclusive consulting arrangement with Dr. Mayr, and not with his employer, supports our understanding. I would be pleased to provide to you a copy of Dr. Mayr's 12 September letter.

In addition, according to our records the NIAID has not entered into any agreement with Bavarian Nordic that relates to NIAID's use or distribution of the materials that were the subject of your 8 Apr 2002 facsimile transmittal to Ms. Linda Gritz.

As you are aware research on and development of vaccines, particularly vaccines to combat smallpox and HIV infection, are top priorities for NIAID. In light of the urgent worldwide public health need for such vaccines, and based on the documentation noted above, NIAID will continue its research and development efforts as planned.

Thank you very much for your assistance with this matter. Please do not hesitate to contact me if you have any questions or concerns.

Regards,

Michael

-----Original Message-----

From: Michael Mowatt

Sent: Wednesday, April 24, 2002 4:59 PM

To: 'Peter Wulff'

Subject: RE: 8 Apr 2002 facsimile to Dr. B. Moss

Peter,

It was a pleasure to speak with you last Friday on the subject of MVA. I truly appreciate your efforts to assist me in gathering information about the materials that A Mayr provided to B Moss.

I understood from our conversation that you would provide to me this week by facsimile transmittal several pertinent documents. I write to confirm that you will provide the following:

- 1) 10 Jan 2002 letter from L Gritz to A Mayr
- 2) 26 Feb 2002 letter from L Gritz to A Mayr

3) Agreement(s) under which A Mayr has transmitted materials to B Moss

In addition to these documents I was hoping you could provide more information about the nature of A Mayr's relationship with Bavarian Nordic. I think this will help clarify the context in which the transfer of materials took place.

Thank you again for your helpful assistance. I look forward to hearing from you this week.

Regards,

Michael

-----Original Message-----

From: Peter Wulff [mailto:pw@Bavarian-Nordic.dk]

Sent: Friday, April 19, 2002 5:12 AM

To: Michael Mowatt; Peter Wulff

Subject: RE: 8 Apr 2002 facsimile to Dr. B. Moss

Dear Mr. Wulff,

I can now see why you have questions, since you never received copies of the letters sent by Therion (Linda Gritz) to Anton Mayr. Let us talk about it over the phone. You may call me today between 8 and 11 am your time on +45 33 26 83 83.

Regards

Peter Wulff

-----Original Message-----

From: Michael Mowatt [mailto:MMOWATT@niaid.nih.gov]

Sent: 16. april 2002 15:50

To: Peter Wulff (E-mail)

Subject: 8 Apr 2002 facsimile to Dr. B. Moss

Importance: High

Peter Wulff,
CEO, Bavarian Nordic A/S

Dear Mr. Wulff,

I attempted to reach you by telephone today but learned that you will be out of the office until Thu, 18 Apr 2002.

Dr. Bernard Moss, an investigator in the Division of Intramural Research at the National Institute of Allergy and Infectious Diseases (NIAID), has forwarded to me your 8 Apr 2002 fax to Ms. Linda Gritz, which you provided to him as a courtesy copy

("cc"). I have several questions about this correspondence and would like to discuss it with you at your earliest convenience.

I would be pleased to call you on Thu, 18 Apr or Fri, 19 Apr at a time that is convenient for you. By my calculations you are six hours ahead of us here (<http://www.worldtimeserver.com/>). Please let me know your availability to discuss this matter.

Thank you very much for your assistance. I look forward to speaking with you soon.

Regards,

Michael R. Mowatt, Ph.D.
Director, Office of Technology Development

**National Institute of Allergy and Infectious
Diseases**
National Institutes of Health
U.S. Department of Health and Human Services

Building 31 Room 3B62 Tel: 301/496-2644
31 Center Drive MSC 2137 Fax: 301/402-7123

Bethesda MD 20892-2137
<http://www.niaid.nih.gov/ttb/ttb.htm>

EXHIBIT 34

NOV-15-2002 18:26

NIH/NIH/D/LUD

361 480 1147 P.03

Prof. Dr. Dr. h.c.mult. Anton Mayr
Inst. For Medical Microbiology and Infectious
Diseases
Veterinary Faculty University Munich
Veterinaerstrasse 13
Munich 80539
Germany

Dr. Bernard Moss
Laboratory of Viral Diseases
DIR, NIAID, NIH
Building 4, Room 229
4 Center Drive
MSC 0445
Bethesda, MD 20892-0445
USA

Beforehand by fax: (301) 4801 147

6th November 2002

Ref. MVA and uses thereof

Dear Dr Moss

I am writing to enquire about recent events that have come to my attention regarding the commercialization by the NIH of MVA as a safe smallpox vaccine. Under the recent RFP (NIH-NIAID-DMID-03-44) it states that the NIH is willing to provide successful applicants a MSV of MVA for the development of a smallpox vaccine and I have recently discovered that the NIH is funding a Phase I clinical program. I assume from the recent reports of your involvement with Dr Jahrling (USAMRIID) for the purposes of performing a primate monkey pox study that this source of MVA has been provided by yourself, derived from the various stocks of MVA which I have provided to you in the past.

I am a little surprised by these events as I have provided MVA to academic partners for research purposes only. You initially received MVA from the time Dr Sutter (Postdoctoral Fellow working for me) visited your laboratory through a German grant that I was awarded during 1990. Upon your request for other sources of MVA for 'expression vector work' I provided MVA 575 and MVA II/85 in 1995 and MVA 572 during 2001. I have always been willing to collaborate with you in the past, but MVA was only ever provided to support your academic research at the NIH. From recent letters I have received from Therion (Jan & Feb 2002) requesting my permission to allow you to provide them MVA 572, I thought you fully understood that the MVA I provided was for academic research purposes only.

NIH00325

NOV-15-2002 18:27

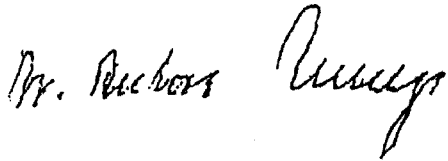
NIH/NIAD/LUD

301 480 1147 P.04

Several MVA strains, including MVA 572, were deposited by myself in the European tissue culture collection which prohibits the commercialization of the deposited strain, or their derivatives, without the written permission from the organization, or individual that deposited the virus. Furthermore, I have provided an exclusive license for the commercialization of all MVA strains to Bavarian Nordic and therefore your disregard for our long-standing collaboration has put me in a compromised position with the company I have been working with since 1997. I am also disappointed as MVA represents a significant achievement in my scientific career and while I am happy to see people working with my invention I am disappointed to think that I would not be recognized for my achievements should MVA be commercialized by the NIH, or by other companies that have received sources of MVA strictly meant for research purposes.

I would appreciate an update of your activities using any of the MVA strains, or their derivatives that I have provided to you over the years.

Yours sincerely



Prof. Dr. Dr. h.c. mult. Anton Mayr
Lehrstuhl für Mikrobiologie
und Seuchenlehre
Veterinärstraße 13
80539 München

Prof. Dr. Dr. h.c. mult. Anton Mayr

TOTAL P.04

NIH00326

Prof. Dr. Dr. h.c.mult. Anton Mayr
Inst. For Medical Microbiology and Infectious
Diseases
Veterinary Faculty University Munich
Veterinaerstrasse 13 -
Munich 80539
Germany

Michael Mowatt Ph.D
Dir. Office of Technology Development
NIH, NIAID
Building 31 Room 3B62
31 Center Drive MSC 2137
Bethesda MD 20892-2137
USA

Beforehand by fax. (301) 402 7123

6th November 2002

Re: MVA and uses thereof

Dear Dr Mowatt,

I am writing to enquire about recent events that have come to my attention regarding the commercialization by the NIH of MVA as a safe smallpox vaccine. Under the recent RFP (NIH-NIAID-DMID-03-44) it states that the NIH is willing to provide successful applicants a MSV of MVA for the development of a smallpox vaccine and I also understand that the NIH is funding a Phase I clinical program. In this RFP it requests evidence that the 'offeror has secured access to all intellectual property, know-how and tangible materials for the proposed work'.

I would like clarification why the NIAID believes it has access to all rights for the MVA that I supplied Dr Moss. Initially I provided Dr Moss with MVA from the time Dr Sutter (Postdoctoral Fellow working for me) visited his laboratory during 1990-93, although this academic research was funded by a German grant I was awarded in 1990. Upon further requests from Dr Moss for other sources of MVA for 'expression vector work' I provided MVA 575 and MVA II/85 in 1995 and MVA-572 during 2001. Again this was requested for research purposes and supplied in the knowledge that several MVA strains including MVA 572 were already deposited in European tissue culture collection which prohibits the commercialization of the deposited strain, or their derivatives, without the written permission from the organization, or individual that deposited the virus.

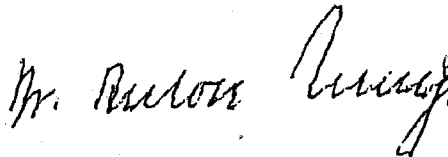
The fact that I have also received several requests from Therion to allow permission for Dr Moss to hand over MVA, also suggests that Dr Moss fully understood that all MVA strains supplied to him were for academic research purposes only. With these facts I was

of the understanding that the MVA strains which I supplied to Dr Moss were for research purposes only and would not be handed out for commercialization.

I have been working with Bavarian Nordic since 1997 as a full consultant and have provided them the exclusive rights for MVA. On my behalf Mr Wulff (President & CEO) wrote to Therion to clarify my position and deny access to the MVA strains requested (MVA-572) from Dr Moss. Your response dated 15th July clearly lacks the historical facts, ignores my long-term relationship with Bavarian Nordic and the fact these strains have been deposited in European tissue culture collections for many years. I therefore request a clarification from the NIAID why you believe there are 'no limitations on its ability to use and distribute the material, progeny or derivatives of the material'.

I agree with your statement that MVA represents an excellent candidate for the development of vaccines against HIV and smallpox infections. However, evidence from Bavarian Nordic suggests that MVA-BN has superior safety features and therefore I even have scientific reservations of the development of other MVA strains, especially for immune compromised individuals. The complete disregard by the NIH for the rights of a scientist who supplied material to a fellow scientific colleague for research purposes is something I am sure would damage the reputation of Dr Moss and the NIH. I am disappointed to think that I would not be recognized for my achievements should MVA be commercialized by the NIH, or by other companies that have received sources of MVA strictly meant for research purposes.

Yours sincerely


Prof. Dr. Dr. h.c. mult. Anton Mayr
Lehrstuhl für Mikrobiologie
und Seuchenlehre
Veterinärstraße 13
80539 München

Prof. Dr. Dr.h.c.mult. Anton Mayr

cc: J. La Montague, Deputy Director, NIAID
R. Lambert, Office of the General Counsel, NIH
M. Rohrbaugh, Acting Director, Office of Technology Transfer, NIH

Prof. Dr. Dr. h.c.mult. Anton Mayr
Inst. For Medical Microbiology and Infectious
Diseases
Veterinary Faculty University Munich
Veterinaerstrasse 13
Munich 80539
Germany

John R. La Montague, Ph.D
Deputy Director
Office of Technology Development
NIH, NIAID
Building 31 Room 7A03
31 Center Drive MSC 2137
Bethesda MD 20892-2137
USA

Beforehand by fax. (301) 496 4409

6th November 2002

Re: MVA and uses thereof

Dear Dr Montague,

I am writing to enquire about recent events that have come to my attention regarding the commercialization by the NIH of MVA as a safe smallpox vaccine. Under the recent RFP (NIH-NIAID-DMID-03-44) it states that the NIH is willing to provide successful applicants a MSV of MVA for the development of a smallpox vaccine and I also understand that the NIH is funding a Phase I clinical program. In this RFP it requests evidence that the 'offeror has secured access to all intellectual property, know-how and tangible materials for the proposed work'.

I would like clarification why, the NIAID believes it has access to all rights for the MVA that I supplied Dr Moss. Initially I provided Dr Moss with MVA from the time Dr Sutter (Postdoctoral Fellow working for me) visited his laboratory during 1990-93, although this academic research was funded by a German grant I was awarded in 1990. Upon further requests from Dr Moss for other sources of MVA for 'expression vector work' I provided MVA 575 and MVA II/85 in 1995 and MVA-572 during 2001. Again this was requested for research purposes and supplied in the knowledge that several MVA strains including MVA 572 were already deposited in European tissue culture collection which prohibits the commercialization of the deposited strain, or their derivatives, without the written permission from the organization, or individual that deposited the virus.

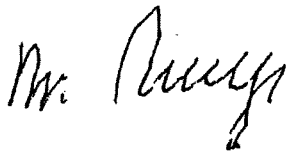
The fact that I have also received several requests from Therion to allow permission for Dr Moss to hand over MVA, also suggests that Dr Moss fully understood that all MVA

strains supplied to him were for academic research purposes only. With these facts I was of the understanding that the MVA strains which I supplied to Dr Moss were for research purposes only and would not be handed out for commercialization.

I have been working with Bavarian Nordic since 1997 as a full consultant and have provided them the exclusive rights for MVA. On my behalf Mr Wulff (President & CEO) wrote to Therion to clarify my position and deny access to the MVA strains requested (MVA-572) from Dr Moss. Your response dated 15th July clearly lacks the historical facts, ignores my long-term relationship with Bavarian Nordic and the fact these strains have been deposited in European tissue culture collections for many years. I therefore request a clarification from the NIAID why you believe there are 'no limitations on its ability to use and distribute the material, progeny or derivatives of the material'.

I agree with your statement that MVA represents an excellent candidate for the development of vaccines against HIV and smallpox infections. However, evidence from Bavarian Nordic suggests that MVA-BN has superior safety features and therefore I even have scientific reservations of the development of other MVA strains, especially for immune compromised individuals. The complete disregard by the NIH for the rights of a scientist who supplied material to a fellow scientific colleague for research purposes is something I am sure would damage the reputation of Dr Moss and the NIH. I am disappointed to think that I would not be recognized for my achievements should MVA be commercialized by the NIH, or by other companies that have received sources of MVA strictly meant for research purposes.

Yours sincerely



Prof. Dr. Dr. h.c. mult. Anton Mayr
Lehrstuhl für Mikrobiologie
und Seuchenlehre
Veterinärstraße 13
80539 München

Prof. Dr. Dr.h.c.mult. Anton Mayr

cc: M. Mowatt, Director, NIAID
R. Lambert, Office of the General Counsel, NIH
M. Rohrbaugh, Acting Director, Office of Technology Transfer, NIH

EXHIBIT 35



15 July 2002

→ PC/H

Received in
FIN 9/S
25 JUL 2002

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

OFFICE OF TECHNOLOGY
DEVELOPMENT

Building 31 Room 3B62
31 Center Drive MSC 2137
Bethesda MD 20892-2137

Tel: (301) 496-2644
Fax: (301) 402-7123

VIA FACSIMILE TRANSMITTAL WITH CONFIRMATION VIA COURIER

Fax +45 33 26 83 80, Tel +45 33 26 83 83

Peter Wulff
Bavarian Nordic A/S
Vesterbrogade 149
DK-1620 Copenhagen V
DENMARK

RE: MVA 572.FHE – 22.02.1974

Dear Mr. Wulff:

I write to summarize my understanding of the conditions under which the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health received from Prof. Dr. Dr. h.c. mult. Anton Mayr, Lehrstuhl für Mikrobiologie und Seuchenlehre, Ludwig-Maximilians-Universität München, the lyophilized preparation of vaccinia virus MVA known as "MVA 572.FHE – 22.02.1974." In addition, I write to confirm the NIAID's intention to use and make available to other parties progeny and derivatives of the material that have been developed by Dr. Bernard Moss, Chief of the Laboratory of Viral Diseases, Division of Intramural Research, NIAID.

As you are aware, in response to a request by Dr. Moss, in August 2001 Dr. Mayr provided one vial of lyophilized tissue culture material originating from the vaccinia virus MVA as described by Mayr, et al. in 1975 (Passage history, properties and applicability of the attenuated vaccinia virus strain MVA, *Infection*, 3:6-14). In response to Dr. Moss's request for documentation about the material, Dr. Mayr provided to Dr. Moss a letter dated 12 September 2001, a copy of which is enclosed. Like the 19 September 1995 letter, also enclosed, under which Dr. Mayr supplied a sample of a 1983 passage of the same virus strain, the 12 September 2001 letter specifies no limitations on the use or distribution of the material by the NIAID.

→ But "Resumption" also

Since you and I first discussed this subject by telephone on 19 April 2002 I have sought to obtain from you documentation to support Bavarian Nordic's assertion that NIAID's ability to use and distribute the material is somehow limited. This suggestion is reflected in your 9 April 2002 facsimile transmittal to Dr. Linda Gritz, Principal Scientist, Therion Biologics Corporation, of which Dr. Moss received a courtesy copy (enclosed), and was reinforced by you during our 19 April conversation. In our conversation you indicated that Dr. Mayr had provided the material to NIAID under a Material Transfer Agreement and, further, that Bavarian Nordic had acquired all MVA materials in possession of Dr. Mayr

→ That was what I thought

P. Wulff/Bavarian Nordic A/S

Page 1 of 2

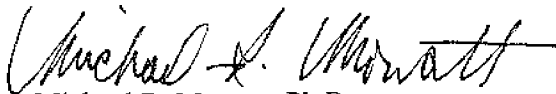
through an exclusive consulting arrangement. Your failure to supply such documentation despite my numerous requests for copies of the documentation (see my 24 April 2002, 8 May 2002 and 28 May 2002 electronic mail messages, which are enclosed) leads me to conclude that the documentation does not exist.

In summary, according to our records the NIAID received "MVA 572.FHE – 22.02.1974" from Dr. Mayr under the 12 September 2001 letter that specifies no limitations on the NIAID's use and distribution of the material or of progeny or derivatives of the material. In addition, I have found no evidence of an agreement between NIAID and Bavarian Nordic that relates to or would limit in any way the NIAID's use and distribution of the material supplied by Dr. Mayr. Accordingly, the NIAID recognizes no limitations on its ability to use and distribute the material, progeny or derivatives of the material. The Office of the General Counsel at the National Institutes of Health has reviewed this letter and the supporting documentation referenced herein and concurs with the NIAID's position.

As you know, research on and development of vaccines, including vaccines to combat HIV infection as well as smallpox and other potential agents of biological warfare, are among the very highest priorities of the NIAID. In light of the urgent worldwide public health need for such vaccines, particularly those based upon MVA, the NIAID intends to use the material supplied by Dr. Mayr for research and development projects both internally and in collaborations with organizations in the public and private sectors. In addition, the NIAID intends to distribute to qualified requestors progeny and derivatives of the material that have been and will be created by Dr. Moss and/or contractors of the NIAID in order to facilitate and expedite research and development projects that are dependent upon such materials.

Please do not hesitate to contact me should you have any questions or if I can assist you in the future.

Sincerely,



Michael R. Mowatt, Ph.D.

Director

Office of Technology Development

Enclosures (6)

cc: J. La Montagne, Deputy Director, NIAID
B. Moss, DIR, NIAID
R. Lambert, Office of the General Counsel, NIH
M. Rohrbaugh, Acting Director, Office of Technology Transfer, NIH
A. Mayr, Ludwig-Maximilians-Universität München

EXHIBIT 36

CONFIDENTIAL EXHIBIT

EXHIBIT 37

National Institutes of Health
National Institute of Allergy and Infectious Diseases
Building 31 Room 7A03
31 Center Drive
Bethesda, MD 20892-2520
United States of America
Attn.: John R. La Montagne

March 27, 2003

Dear John R. La Montagne,

MVA – Intellectual Property

To follow up on our meeting on January 8, 2003 we write to thank you for acknowledging the fact that your sample of MVA 572 was received from Anton Mayr for research purposes.

This confirms the intent of the inventor and our consultant, A. Mayr and that of the original recipient, B. Moss as memorialized by the correspondence by the company, Therion Biologics of February 26, 2002. In this letter, Therion Biologics asks A. Mayr's permission for B. Moss to provide a sample of MVA 572 which we subsequently rejected.

Furthermore we understand that you have released this sample to Acambis without our permission but also without any warranty or assurances to Acambis as for the right to use or commercialize this sample. We enclose our latest correspondence with Acambis in this regard and accordingly await their comments as to how they would fulfill the requirements in order to secure access to all necessary intellectual property and know-how under the RFP.

Yours sincerely,

Bavarian Nordic A/S
Peter Wulff
President & CEO

cc.
Michael R. Mowatt
B. Moss
R. Lambert
M Rohrbaugh
Helge Lund, Danish Embassy Washington

EXHIBIT 38



National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

30 June 2003

Building 31 Room 7A03
Bethesda MD 20892

VIA FACSIMILE TRANSMITTAL, WITH CONFIRMATION VIA COURIER

Fax +45 33 26 83 80, Tel +45 33 26 83 83

Peter Wulff
Bavarian Nordic A/S
Ved Amagerbanen 23
DK-2300 Copenhagen S
DENMARK

RE: MVA – Intellectual Property

Dear Mr. Wulff:

It was a pleasure to meet with you and Dr. Paul Chaplin during your visit to the National Institute of Allergy and Infectious Diseases (NIAID) on 8 January 2003. My colleagues and I found the meeting both interesting and informative, and we believed we had made meaningful progress toward clarifying for you the circumstances under which the NIAID received "MVA 572.FHE-22.02.1974" from Dr. Anton Mayr in 2001. For this reason I was surprised and disturbed to receive your letter, dated 27 March 2003, which you describe as a "follow up on our meeting on January 8, 2003." You state that the MVA 572 sample "was received from Anton Mayr for research purposes" and that the NIAID has released this sample to Acambis without the permission of Bavarian Nordic and without any warranty or assurances to Acambis as to the right to use or commercialize the sample.

As Dr. Michael Mowatt, Director of the NIAID Office of Technology Development, clearly stated in his letter to you dated 15 July 2002 and as we discussed in our meeting on 8 January 2003, the NIAID received "MVA 572.FHE-22.02.1974" from Dr. Mayr under a cover letter dated 12 September 2001 that specifies no limitations on the NIAID's use and distribution of the material or of the progeny or derivatives of the material. In addition, we have no evidence of an agreement between NIAID and Bavarian Nordic that relates to or limits in any way the NIAID's use and distribution of the material supplied by Dr. Mayr. Accordingly, as we have stated before, the NIAID may use and distribute the material, progeny or derivatives of the material without limitation, and does not require the permission of Bavarian Nordic for use and distribution of the material, progeny or derivatives of the material.

P. Wulff/Bavarian Nordic A/S

Page 1 of 1

During our meeting on 8 January 2003 you and Dr. Chaplin described to my colleagues and me Bavarian Nordic's preliminary findings pertinent to the safety profile of MVA. We emphasized the importance of subjecting these findings to the peer review process and, assuming the results meet the scrutiny of peer review, we encouraged the rapid publication of the information. In our meeting you indicated that you were planning to publish these results in *Science* early in 2003. I would be grateful to receive an update on the status of your publication.

As you know research on and development of vaccines, including vaccines to combat HIV infection as well as smallpox and other potential agents of biological warfare, are among the very highest priorities of the NIAID. In light of the urgent worldwide public health need for such vaccines, particularly those based upon MVA, the NIAID intends to use the material supplied by Dr. Mayr for research and development projects both internally and in collaborations with organizations in the public and private sectors. In addition, the NIAID intends to distribute to qualified requestors progeny and derivatives of the materials that have been and will be created by Dr. Moss and/or contractors of the NIAID in order to facilitate and expedite research and development projects that are dependent upon such materials.

Please do not hesitate to contact me should you have any questions or if I can assist you in the future.

Sincerely,



John R. La Montagne, Ph.D.
Deputy Director

National Institute of Allergy and Infectious Diseases
National Institutes of Health

cc: M. Mowatt, OTD, NIAID
B. Moss, DIR, NIAID
S. Sherman, Office of the General Counsel, NIH
M. Rohrbaugh, Director, Office of Technology Transfer, NIH
H. Lund, Royal Danish Embassy, Washington, DC

EXHIBIT 39

EXHIBIT A

MATERIALS TRANSFER AGREEMENT

This Agreement is entered into between the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute of the National Institutes of Health ("NIH"), which is part of the U.S. Public Health Service ("PHS") and the Department of Health and Human Services ("DHHS"), an agency of the U.S. Government, having an address at 31 Center Drive, Room 3B62, Bethesda, Maryland 20892, U.S.A. and Acambis, Inc. ("Recipient"), a corporation of Delaware, having an office at 38 Sidney Street, Cambridge, MA 02139.

1. Definitions:

- a. "Materials" means the following biological materials: Modified Vaccinia Ankara (MVA) virus 572.FHE-22.02.1974, as described in Mayr et al., Passage history, properties and applicability of the attenuated vaccinia virus strain MVA, *Infection* 3: 6-14 (1975) and which was plaque purified by Dr. Bernard Moss of the NIAID.
- b. "Commercial Products" means a Modified Vaccinia Ankara (MVA) Vaccine, which includes Materials or its derivatives.

2. Recipient wishes to use the Materials provided under this Agreement in its internal commercial research, product development and marketing of Commercial Products. Recipient represents that it has the facilities, personnel, and expertise to use the Materials for such commercial purposes and agrees to expend reasonable efforts and resources to develop Commercial Products in a timely manner using the Materials.
3. NIAID hereby grants to Recipient worldwide, non-exclusive rights to make, have made, and use the Materials and to make and have made, to use and have used, to sell and have sold, and to offer to sell Commercial Products in the Field of Use of Smallpox Vaccines.
4. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of NIAID's written information about the Materials that is stamped "CONFIDENTIAL," except for information that was previously known to Recipient or that is or becomes publicly available or which is disclosed to Recipient without a confidentiality obligation. Any oral disclosures from NIAID to Recipient shall be identified as being CONFIDENTIAL by notice delivered to Recipient within ten (10) days after the date of the oral disclosure. Recipient may publish or otherwise publicly disclose the results of its research activities with the Materials, but if NIAID has given CONFIDENTIAL information to Recipient such public disclosure may be made only after NIAID has had thirty (30) days to review the proposed disclosure to determine if it includes any CONFIDENTIAL information, except when a shortened time period under court order pertains.
5. Recipient agrees to provide a written report to NIAID within sixty (60) days after the end of each calendar year during the term of this Agreement. This report shall document the progress made towards producing a smallpox vaccine and list all activities and results obtained using the Materials during the preceding calendar year. Recipient shall submit these reports to NIAID at the Mailing Address for Notices indicated on the Signature Page of this Agreement.
6. Recipient agrees to provide, at no charge, the laboratory of Dr. Bernard Moss at NIAID reasonable quantities of Materials and Commercial Products that Recipient makes, uses, sells, or offers for sale or otherwise makes available for public use under terms no more restrictive than those of the NIH Simple Letter Agreement (Federal Register [64 FR 72090]) (Attached).
7. Recipient agrees to retain control over the Materials, and not to distribute them to third parties without the prior written consent of NIAID except as permitted in Paragraph 3.
8. Recipient agrees that this Agreement does not preclude NIAID from distributing the Materials to third parties for research or commercial purposes.

NIAID Biological Materials Transfer Agreement CONFIDENTIAL
Model 020803 Page 1 of 3 ~~Darter-NIAID 02-08-20~~

Acambis

Acambis, Inc.

Response to RFP NIH-NIAID-DMID-03-44
September 27 2002

4a

AC0006735

9. By this Agreement, NIAID grants no patent rights expressly or by implication to any anticipated or pending NIAID patent applications or issued patents.
10. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS PROVIDED TO RECIPIENT UNDER THIS AGREEMENT, OR THAT THE MATERIALS OR COMMERCIAL PRODUCTS MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. Recipient accepts transfer of the Materials "as is", and NIAID does not offer any guarantee of any kind.
11. Recipient agrees to indemnify and hold harmless the United States Government from any claims, costs, damages, or losses that may arise from or through Recipient's use of the Materials or Commercial Products. Recipient further agrees that it will not by its action bring the United States Government into any lawsuit involving the Materials or Commercial Products.
12. Recipient agrees in its use of Materials to comply with all applicable statutes, regulations, and guidelines, including PHS and DHHS regulations and guidelines. Recipient agrees not to use the Materials or the Commercial Products for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. Recipient agrees not to use the Materials or Commercial Products for research involving human subjects or clinical trials outside of the United States without notifying NIAID, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to NIAID of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.
13. Recipient may terminate this Agreement upon sixty (60) days written notice to NIAID.
14. NIAID may terminate this Agreement if Recipient is in default in the performance of any material obligation under this Agreement, and if the default has not been remedied within ninety (90) days after the date of written notice by NIAID of such default.
15. Upon termination of this Agreement, Recipient agrees to return all Materials and Commercial Products to NIAID, or provide NIAID with certification of their destruction.
16. Within ninety (90) days of termination of this Agreement, Recipient agrees to submit a final report to NIAID, that specifies all activities and results related to use of Materials and Commercial Products by Recipient.
17. This Agreement shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement. Recipient agrees to be subject to the jurisdiction of U.S. courts.
18. This Agreement constitutes the entire understanding of NIAID and Recipient and supersedes all prior agreements and understandings with respect to the Materials.
19. This Agreement shall become effective on the date when the last party has signed this Agreement.
20. The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions of this Agreement.
21. Paragraphs 4, 10, 11, 12, 15, 17, 18, 20, and 21 shall survive termination of this Agreement.

SIGNATURES BEGIN ON NEXT PAGE

NIAID Biological Materials Transfer Agreement CONFIDENTIAL
Model 020808 Page 2 of 3

Acambis

Acambis, Inc.

Response to RFP NIH-NIAID-DMID-03-44
September 27 2002

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AC0006736

NIAID BIOLOGICAL MATERIALS TRANSFER AGREEMENT

SIGNATURE PAGE

In Witness Whereof, the parties have executed this Agreement on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For NIAID:

Michael R. Mowatt
Michael R. Mowatt, Ph.D.
Director, Office of Technology Development

11 SEP 2002
Date

Mailing Address for Notices: OFFICE OF TECHNOLOGY DEVELOPMENT
NIAID, NIH
Building 31 Room 3B62
Bethesda MD 20892-2137

Tel: 301/496-2644 Fax: 301/402-7123

For Recipient (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of Recipient made or referred to in this document are truthful and accurate.):

By: Stephen H. Atkinson
Stephen H. Atkinson
Vice President, Commercial Development

9/10/02
Date

Stephen H. Atkinson
Printed Name

Mailing Address for Notices: Acambis, Inc.
38 Sidney Street
Cambridge, MA 02139

Any false or misleading statements made, presented, or submitted to the U.S. Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1901 (criminal liability including fine(s) and/or imprisonment).

EXHIBIT 40

CONFIDENTIAL EXHIBIT

EXHIBIT 41

CONFIDENTIAL EXHIBIT

EXHIBIT 42



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

17 January 2003

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

OFFICE OF TECHNOLOGY
DEVELOPMENT

6610 Rockledge Drive
Room 4071B
Bethesda MD 20892-6606

Tel: (301) 496-2644
Fax: (301) 402-7123

VIA FACSIMILE TRANSMITTAL WITH CONFIRMATION BY USPS

617/494-1741

Roger J. McAvoy
Government Contracts & Legal Affairs
Acambis Inc.
38 Sidney Street
Cambridge MA 02139

RE: Proposal Revision - Development and Testing of a Modified Vaccinia Ankara (MVA)
Vaccine

Dear Mr. McAvoy:

I write in reference to the Interim Proposal Revision (IPR) that Acambis submitted to the National Institute of Allergy and Infectious Diseases (NIAID) pursuant to Request for Proposals (RFP) number NIH-NIAID-DMID-03-44 under cover of your letter, dated 14 January 2003, to Ms. Jacqueline C. Holden. On page two (2) of the section entitled "Revised IIG" of the IPR with respect to the MVA virus 572.FHE-22.02.1974 (as described in Mayr, et al. "Passage history, properties and applicability of the attenuated vaccinia virus strain MVA, Infection 3:6-14 (1975)), which Acambis received from the NIAID under a NIAID Biological Materials Transfer Agreement dated 11 September 2002, Acambis states the following:

"It is Acambis' understanding that the NIH has undertaken a comprehensive review of intellectual property and other property rights in the MVA field and has determined that the NIH has all rights requisite to granting this license to Acambis."

I write to clarify any misunderstanding regarding NIAID's activities with respect to the material and NIAID's distribution of the material. First, I must emphasize that NIAID has not undertaken a comprehensive review of intellectual property in the MVA field, as your letter suggests. However, prior to distribution of the material NIAID determined that it is within its rights to transfer the material to other parties. In addition I bring to your attention Paragraph 10 of the

OTD/NIAID-Acambis Inc.

17 January 2003

Page 1 of 2

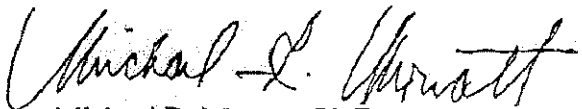
NIAID Biological Materials Transfer Agreement, which appears in the IPR on page 4b of the section entitled "Revised IIG":

"10. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS PROVIDED TO RECIPIENT UNDER THIS AGREEMENT, OR THAT THE MATERIALS OR COMMERCIAL PRODUCTS MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. Recipient accepts transfer of the Materials "as is", and NIAID does not offer any guarantee of any kind."

Accordingly, I urge Acambis to undertake its own analysis of intellectual property and other proprietary rights that Acambis may need in order to develop and commercialize MVA as a smallpox vaccine.

I would be pleased to discuss any questions you might have about this matter, but please note that, because Acambis' application is under consideration, all such communication should occur through Ms. Jacqueline Holden, who is the Contracting Officer for this RFP.

Sincerely,



Michael R. Mowatt, Ph.D.
Director, Office of Technology Development

Enclosure

cc: J. Holden, DEA, NIAID
E. Nuzum, DMID, NIAID

OTD/NIAID-Acambis Inc.

17 January 2003
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EXHIBIT 43

CONFIDENTIAL EXHIBIT

EXHIBIT 44

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EXHIBIT 47

CONFIDENTIAL EXHIBIT

EXHIBIT 48

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EXHIBIT 49

CONFIDENTIAL EXHIBIT

EXHIBIT 50

CONFIDENTIAL EXHIBIT

EXHIBIT 51

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S,

Plaintiff,

v.

ACAMBIS INC. and
ACAMBIS, PLC,

Defendants.

)
)
)
)
) Civil Action No. 05-614
)
)
)
)
)

EXPERT REPORT OF ROBERT DRILLIEN

I. INTRODUCTION

1. My name is Robert Drillien and I hold a position at the Institute of Genetics and Molecular and Cellular Biology (“IGBMC”) in Strasbourg, France, which is one of the leading European Centers for biomedical research. My own research focuses on virology with emphasis on the analysis of vaccinia virus strains such as Modified Vaccinia Ankara (“MVA”).

2. I have been retained as a scientific expert by Bavarian Nordic A/S (“BN”) in connection with the above-referenced lawsuit to study and provide my opinion on certain issues relating to academic research and biopharmaceutical industry practices.

3. I understand that BN claims that a specific biological material referenced to as MVA-572 has been unlawfully converted by Acambis, which I understand is one of the allegations of unfair trade practices raised against Acambis in this case.

and vaccines against smallpox; and vaccines against smallpox and other diseases based on the MVA virus. I am also prepared to testify about how organizations, such as the WHO, and nations respond to smallpox and other threats of disease and biological weapons.

9. I am prepared to testify on the conversion of the MVA-572 strain by Acambis for Acambis' commercial use, the significance of access to this particular MVA strain to achieve an expeditious development of an MVA vaccine product to pursue a Biologic License Application ("BLA") at the FDA. Use of this particular strain because of the year of its creation enables one to avoid certain regulatory hurdles and warning labels relating to bovine spongiform encephalopathy ("BSE") and/or transmissible spongiform encephalopathy ("TSE"). Thus, MVA-572 is an important and desirable MVA virus material.

10. I am prepared to testify about how access to MVA biological material, including the Therion MVA virus or MVA-572, grown up into a seed stock at NIH, was necessary for Acambis to bid on RFP 1, 2 and 3 and receive contracts to supply over 505,000 doses of MVA vaccines to the U.S. Government.

11. I am prepared to testify that Acambis made commercial use of the seed stock received from NIH for Acambis' smallpox vaccine product MVA3000, also sometimes called ACAM3000.

12. I am prepared to testify about research and industry practices regarding the provision of live biological material, such as MVA virus strains, among scientists associated, including scientists associated with research institutions. I am prepared to testify that in such circumstances, without an explicit agreement that the strain may be used for commercial purposes, the live biological material or strain cannot be used for commercial purposes.

13. In particular, it is my opinion that the transfer of live biological material to a

research institution, absent a written agreement, takes place with the understanding that the biological material's use will be limited to research purposes only.

14. Moreover, it is my opinion that it is industry practice for a research institution to enter into an explicit, written agreement, when the exchange of biological material is intended for commercial purposes, such as the development of a commercial product.

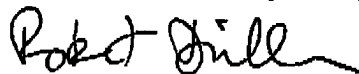
15. I may be called upon to testify about research and industry practices within the scientific community in Europe and the U.S., regarding the provision of live biological material, such as MVA strains, to a research institution. In particular, it is my opinion that the transfer of live biological material to a research institution, absent a written agreement, takes place with the understanding that the biological material's use will be limited to research purposes only. Moreover, it is my opinion that it is industry practice for a research institution to enter into an explicit, written agreement, when the exchange of biological material is intended for commercial purposes, such as the development of a commercial product.

IV. MATERIALS CONSIDERED

16. I have attached to this report a list of materials that I reviewed and considered in forming the basis for my opinions.

17. I reserve the right to continue to review materials that have been produced in this case, and supplement my expected testimony based on the review of such additional materials. I further reserve the right to review the reports of other experts in this case, including any experts put forth by Acambis, and supplement my opinions based on any such reports.

Respectfully submitted, October 12, 2006



Robert Drillien
14 rue Waldteufel
Strasbourg, France

EXHIBIT 52

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BAVARIAN NORDIC A/S,

Plaintiff,

v.

ACAMBIS INC. and
ACAMBIS PLC,

Defendants.

Civil Action No. 05-614 (SLR)

SUPPLEMENTAL EXPERT REPORT AND/OR LEGAL OPINION OF

PROF. DR. DRES. H.C. JOSEPH STRAUS

I. INTRODUCTION

1. My name is Joseph Straus and I have been retained as a legal expert on German Law by Bavarian Nordic A/S (“BN”) in connection with the above-referenced case in the United States District Court for the District of Delaware to study and provide opinion on certain issues relating to ownership to and/or intellectual property rights in certain Modified Vaccinia Virus Ankara (“MVA”) strains and vaccines. On October 2, 2006 I submitted my Expert Report and/or Legal Opinion.

2. After having read the Expert Report and/or Legal Opinion of Prof. Dr. Winfried Tilmann of November 10, 2006, I wish to submit the following supplementary statement.

III. TRANSFER OF OWNERSHIP IN MOVABLES UNDER § 929 BGB

8. According to the case law of the German Federal Supreme Court (BGH) for the *transfer of ownership* in movables it is required that

“the owner of the thing deliver it to the acquirer and that both agree that the ownership is transferred: It suffices, when the will for the transfer of ownership is revealed from the circumstances. Whether the will to agree exists, is to be judged according to the general principles applicable to the interpretation of legal transactions [references omitted].”¹

9. In other words, the question, whether an agreement between the parties concerned as to the transfer of ownership is to be confirmed, depends on the circumstances of the case at issue. This, it has to be emphasized, does not relate to the underlying “causal purpose-agreement” or “any underlying obligatory purpose-agreement,” in Prof. Tilmann’s words, but exclusively to the *separately* and *independently* required agreement as to *the transfer of ownership*. It is also understood that the movable thing in which the ownership is to be transferred has to be specifically individualized since only in such objects a possession is possible. Therefore, ownership transfer in a quota of a larger quantity is not possible. § 929 BGB requires a separation of the specific objects.²

¹ 1990 NJW 1913, left column. In the original German: “... Zur Übertragung des Eigentums an einer beweglichen Sache [ist] erforderlich, dass der Eigentümer die Sache dem Erwerber übergibt und beide darüber einig sind, dass das Eigentum übergehen soll. Es reicht aus, wenn der Wille zur Eigentumsübertragung sich aus den Umständen ergibt. Ob dieser Einigungswille vorhanden ist, beurteilt sich nach den allgemeinen Grundsätzen der Auslegung von Rechtsgeschäften“ [references omitted]. Cf. also Staudinger/Wiegand, 2004, § 929 No. 9 a), with further references.

² Erman/Michalski, § 929 BGB No. 2, with further references to the case law of the former Reichsgericht and the BGH.

10. In the case at hand the circumstances decisive for whether an agreement *as to the transfer of ownership in MVA-572* existed in the sense of § 929 BGB cannot be reduced to the circumstances taken into account by Prof. Tilmann, i.e. to the letter of Prof. Mayr to Dr. Moss dated September 12, 2001. Rather the following circumstances count:

(i) Prof. Mayr deposited the MVA-572-strain with the European Collection of Cell Cultures (ECACC) on *January 27, 1994*, accession number 94012707. Under the rules of ECACC, the deposited strains can be accessed and released without the depositor's consent, but only for use for research purposes.

(ii) Prof. Mayr on *May 28, 1996* signed an Agreement with Bavarian Nordic, in which under No. 1.3 he offered Bavarian Nordic the *exclusive* and *sole access to MVA Vaccine Stock* and MVA Viral Stock in his possession. However, under the very same provision of that agreement it is stated:

“Bavarian Nordic recognizes that, in the scientific community, there is a growing interest in performing basic non-commercial research including the MVA-vector. Bavarian Nordic agrees not to unreasonably use its exclusivity to the MVA-system to hinder basic research by third party non-commercial academia including the MVA-system by rejecting access to the MVA-system.”

This provision is found literally in all agreements which Prof. Mayr subsequently concluded with Bavarian Nordic in June 1996, June 1999, June 2001 as well as June 2003.

(iii) With a letter dated *September 18, 1995*, Therion Biologics requested Prof. Mayr his MVA-strain of Vaccinia Virus. In the request they emphasized that “we will use this material ‘for research purposes only.’” With the accompanying letter of September 26, 1995 Prof. Mayr sent to Mrs. Linda Gritz of Therion Biologics Corporation the requested material, without any further explanation.

(iv) With a letter dated *September 14, 1995*, i.e. after the MVA-572 had been deposited with ECACC, Dr. Moss, Chief of the Laboratory of Viral Diseases of NIH, wrote to Prof. Mayr:

“As you know, my laboratory has been using the MVA-strain of Vaccinia Virus *to make recombinant expression vectors*. Until now, we have been using the virus that was brought here by Gerd Sutter. However, it would be useful to have either an official vial of seed virus used for human vaccine production or a vial of vaccine. If you could supply me with such virus including lot number and date of preparation, it would be greatly appreciated. For your convenience, you could use my Federal Express Numbers to send the material. ...

Thank you for considering this request.”³

(v) With the accompanying letter of *September 19, 1995*, Prof. Mayr sent Dr. Moss the required material, without any comments.

(vi) With a letter dated *August 3, 2001* Dr. Moss again wrote to Prof. Mayr:

“Gerd Sutter told me the good news that you have been able to locate an early sample of MVA in your freezer and have agreed to send it to me. I wish to thank you for your generosity in this regard. As you are aware, MVA has taken on a new life as the premier vaccinia virus vector. I have enclosed a reprint of a recent paper that clearly illustrates the great potential value of MVA. ...

Again, I thank you for your kindness in this matter.”

(vii) Prof. Mayr with accompanying letter of *September 12, 2001*, without specific comments sent the requested material to Dr. Moss.

(viii) National Institutes of Health (NIH) is the largest research institution in life sciences not only in the US, but worldwide. It is a non-for profit institution.

Because of its first-class cutting edge research, Prof. Mayr sent, supported by a grant which he received from the German Public Funding Authorities, his collaborator Gerd Sutter, to NIH, primarily with the task to sequence their MVA-strain of Vaccinia Virus.

(ix) NIH has an Office of Technology Development at the National Institute of Allergy and Infectious Diseases (NIAID). According to its homepage⁴

“The NIAID Office of Technology Development (OTD) accomplishes technology transfer by facilitating the transfer of significant research advances and resources to the broader scientific community and the development of collaborative relationships between NIAID scientists, industry, and academia. NIAID uses various mechanisms to accomplish these ends, including Material Transfer Agreements (MTAs), Co-Operative Research and Development Agreements (CRADAs), Materials-CRADAs (M-CRADAs), Confidential Disclosure Agreements (CDAs), Clinical Trial Agreements (CTAs), Drug Screening Agreements (DSAs), Research Collaboration Agreements (RCAs), and, through the NIH Office of Technology Transfer (OTT), the patenting of inventions and the negotiation of various license agreements.”

(x) NIAID’s OTD, as the commercial exploitation arm of NIH’s NIAID never on its own initiative approached Prof. Mayr, nor was it, at least not visibly, involved in any communication between Dr. Moss and Prof. Mayr.

(xi) On *January 10, 2002* Dr. Linda Gritz, Principle Scientist of Therion Biologics wrote to Prof. Mayr, *inter alia*:

“As per our telephone conversation, I am writing to request several vials of your MVA-strain of Vaccinia Virus that were made before 1980. We

³ Emphasis added.

⁴ <http://www.3.niaid.nih.gov/about/organization/odoffices/omo/otd/about/detel/default...> (last visited November 28, 2006).

are interested in testing recombinant MVA for research in human clinical trials and I am very grateful for the 1983 stocks of MVA that you sent us several years ago. However, the United States Food and Drug Administration is concerned about the possible presence of prions in cell culture material derived in Europe after 1980. Therefore we are requesting earlier (1973 or 1974 or earlier?) stocks of your MVA. We will use this material for research purposes only.”

(xii) In a letter dated February 26, 2002, the same Dr. Gritz of Therion wrote to Prof. Mayr:

“As per our telephone conversation, I am writing about the MVA virus, MVA-572. CEF v. 22.2.74, that you sent to Dr. Bernard Moss. Dr. Moss is willing to send us the virus but would like *written permission from you before he sends us the virus.*

Therefore I would greatly appreciate it if you would send such a letter, giving Dr. Moss permission to provide MVA-572.CEF v. 22.2.74 (and derivatives) to Therion, at your earliest convenience: [here follow the mailing address of Dr. Moss and Dr. Gritz].”⁵

(xiii) Professor Mayr neither required nor received any compensation for the transfer of possession in MVA-572 to Dr. Moss/NIH.

11. The circumstances of the case at hand, to my understanding, do not allow any other conclusion as that there *was neither an explicit nor an implicit agreement between Prof. Mayr and Dr. Moss/NIH that the ownership in the sample of MVA-572, i.e. the complete control to dispose of it at will, in particular to commercially exploit, e.g. license or sell the progeny of the MVA-572 strain, the possession of which Dr. Moss has acquired in 2001, were to*

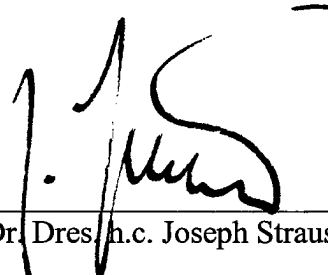
⁵ Emphasis added.

indefinitely. But restrictions apply to further transfers by the recipient.⁷ Thus, the fact alone that a recipient of biological material may destroy it or retain it indefinitely, does not bear any significance as to the ownership in such material.

IV. CONCLUSION

16. Under the case law of the German Federal Supreme Court (BGH) in the case at hand, as a consequence of the *clear lack of a respective agreement*, no transfer of ownership from Prof. Mayr to NIH/Dr. Moss in MVA-572 has taken place under § 929 BGB. This lack of agreement as to the transfer of ownership (“Einigungswille”) relates exclusively and specifically to the so-called “Verfügungsgeschäft”, i.e. the transfer of ownership *in abstracto*.

Munich, November 29, 2006


Prof. Dr. Dres. h.c. Joseph Straus

⁷ O'Connor, The Use of MTAs to Control Commercialization of Stem Cell Diagnostics and Therapeutics, Berkeley Technology Law Journal Vol. 21:3, 1017 ss., at 1019, 1020 [2006].

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 29th day of November 2006, copies of BAVARIAN
NORDIC'S SUPPLEMENTAL EXPERT REPORT AND/OR LEGAL OPINION OF PROF.
DR. DRES. H.C. STRAUS were served as follows:

VIA ELECTRONIC MAIL AND U.S. MAIL :

Mary B. Graham, Esq.
MORRIS, NICHOLS, ARSHT & TUNNELL
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899

William D. Coston, Esq.
VENABLE LLP
575 7th Street, N.W.
Washington, D.C. 20004

John W. Shaw, Esq.
Karen L. Pascale, Esq.
YOUNG CONAWAY STARGATT & TAYLOR
1000 West Street, 17th Floor
Wilmington, DE 19801



Krista L. Lynch
BINGHAM McCUTCHEN LLP
3000 K Street, N.W.
The Washington Harbour
Washington, D.C. 20007
(202) 424-7500

EXHIBIT 53

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EXHIBIT 54

CONFIDENTIAL EXHIBIT

EXHIBIT 55

CONFIDENTIAL EXHIBIT

EXHIBIT 56

CONFIDENTIAL EXHIBIT

EXHIBIT 57

Krista L. Lynch
Direct Phone: (202) 373-6021
Direct Fax: (202) 295-8478
krista.lynch@bingham.com

October 13, 2006

VIA E-MAIL AND U.S. MAIL

Mary B. Graham, Esq.
Morris Nichols, Arsht & Tunnell
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899

William D. Coston, Esq.
Venable LLP
575 7th Street, N.W.
Washington, D.C. 20004

Re: Bavarian Nordic A/S et al. vs. Acambis Inc. et al
Civil Action No. 05-614

Dear Counsel:

Enclosed please find the following:

- Bavarian Nordic A/S' Confidential Third Supplemental Responses to Acambis' First Set of Interrogatories;
- Anton Mayr's First Supplemental Objections and Responses to Acambis First Set of Interrogatories and signed verification; and
- Anton Mayr's curriculum vitae bearing Bates label BNDEL001270-1272.

October 13, 2006
Page 2

Regarding Martin Saad's request that we identify specific provisions of the Delaware Trade Practices Act, Bavarian Nordic identifies Section 2532(a)(1)-(3), (5), (7), (8) and (12) as relevant.

Regards,

A handwritten signature in black ink, appearing to read "Krista L. Lynch". The signature is fluid and cursive, with the first name "Krista" being more prominent.

Krista L. Lynch

Bingham McCutchen LLP
bingham.com

cc: Ed Pennington, Esq.
Robert Bertin, Esq.
John Shaw, Esq.
Martin Saad, Esq.